Jla wbqšY KwgwUi 2 RyjvB 2015 Zwi‡L AbyôZ 244 Zg mfvi Kvhweeiyx

¯v¯¨ I cwievi Kj¨vY gšYvj‡qi mwPe Rbve ‰mq` gbRyj Bmjvg Gu mfvcwZ‡Z Jla wbqšY KwgwUi 244 Zg mfv weMZ 02 RyjvB 2015 Zwi‡L ‡ejv 12:00 NwUKvq gšYvj‡qi mfv K‡¶ AbyôZ nq|

mfvq KwgwUi এর নিম্নবর্ণিত সদস্যগণ উপস্থিত ছিলেন (জ্যেষ্ঠতার ক্রমানুসারে নয়) ঃ

1| Rbve †gvt bvRgyj nvmvb, mfvcwZ, evsjv‡`k Jla wkí mwgwZ, XvKv|
2| Rbve mykxgvi iÄb †Nvl, cwZwbwa, evsjv‡`k dvgwmDwUK¨vjm B‡¤úvUvm G‡mvwm‡qkb, XvKv|
3| Aa¨vcK †gvt kvidzdzb Avn‡¤§`, cwZwbwa, e½eÜz‡kL gyRe †gwW‡Kj wekwe`¨vjq, XvKv|
4| we‡MwWqvi †Rbv‡ij ‡kL i¤ûj Awgb, A¨vKwUs Kbmvj‡U›U wdwRwkqvb ‡Rbv‡ij, evsjv‡`k AvgW †dv‡mm †gwW‡Kj mwf‡mm|
5| Wvt G we Gg kwn` Djvn, c‡¶ gnvcwiPvjK, cwYm¤ú` Awa`ßi, XvKv|
6| Rbve †gvt Awgi †nv‡mb, hyM¥ mwPe, Rb¯v¯¨, ¯v¯¨ I cwievi Kj¨vY gšYvjq|
7| Rbve AvLZvi Avjx miKvi, cwiPvjK (ckvmb), gv`K`e¨ wbqšY Awa`ßi, XvKv|
8| Aa¨vcK Wvt †gvt BmgvBj Lvb, Wxb wPwKrmv Abyj`, XvKv wekwe`¨vjq I cwZwbwa, dvgv‡Kvjwe wefvM, XvKv †gwW‡Kj K‡jR|
9| Aa¨vcK ‡gvt mvBdzj Bmjvg, Wxb, dv‡gmx Abyj`, XvKv wekwe`¨vjq|
10| Aa¨vcK dwi`v †eMg, wKwbK¨vj dv‡gmx I dvgv‡Kvjwe wefvM, XvKv wekwe`¨vjq|
11| Aa¨vcK Wvt RwKi †nvmvBb Mwje, Pg I †hŠb †ivM we‡klÁ, m¨vi mwjgyjvn †gwW‡Kj K‡jR, XvKv|
12| Wvt †gv‡gbyj nK, mv‡eK wmwbqi mn mfvcwZ, evsjv‡`k Jla wkí mwgwZ Ges e¨e¯vcbv cwiPvjK, †Rbv‡ij dvgwmDwUK¨vjm wjt|
13| Rbve Ave`yj †gv³vw`i, mv‡eK gnvmwPe, evsjv‡`k Jla wkí mwgwZ Ges e¨e¯vcbv cwiPvjK, Bb‡mÞv dvgv wjt|
14| Wvt †gvt RvnvsMxi Avjg, †iwR÷vi, evsjv‡`k †nwg lc¨w_K †evW|
15| ‡gRi †Rbv‡ij †gvt ‡gv¯wdRyj ingvb, gnvcwiPvjK, Jla ckvmb Awa`ßi, XvKv|

mfvq Av‡jvP¨ welq mgm¨t

1| weMZ 22-10-2014 Zwi‡L AbyôZ Jla wbqšY KwgwUi 243 Zg mfvi Kvhweeiyx wbwðZKiY cm‡½ (mfvi Kvhweeiyxi Kwc mshy³)|
2| Jla wbqšY KwgwUi †UKwbK¨vj mve KwgwUi MZ 08-06-2015 Zwi‡L AbyôZ 62 Zg Ges 15-06-2015 Zwi‡L AbyôZ 63 Zg mfvi mycwikmg‡ni welq Av‡jvPbv I wm×vš MnY cm‡½ (mfvi Kvhweeiyxi Kwc mshy³)|
3| সভাপতি মহোদয়ের অনুমতিক্রমে যে কোন বিষয়।

mfvq Dcwi D³ welqmgn we¯wiZ Av‡jvPbvcwK wbgewYZ wm×vš MnY Kiv nj t

1| *weMZ 22-10-2014 Zwi‡L Abyôv‡Z Jla wbqšY KwgwUi 243 Zg mfvi Kvhweeiyx wbwðZKiY cm‡½|*

weMZ 22-10-2014 Zwi‡L Abyôv‡Z Jla wbqšY KwgwUi 243 Zg mfvi Kvhweeiyx mfvq Dc¯vcb Kiv nq| Kvhweeiyx mwVKfv‡e wjwce× n‡q‡Q e‡j m`m¨MY gZ cKvk K‡ib|

সভায় সর্বসম্মতিক্রমে ২৪3 *Zg mfvi Kvhweeiyx wbwðZ Kiv nq|*

2.K| mfvq wbgewYZ bZzb JIa Ges cPwjZ JI‡ai bxZb gvÎvi JI‡ai †iwR‡÷kb m¤ú‡K we¯wiZ Av‡jvPbv K‡i wb‡gv³ gZvgZ c`vb Kiv nq t

2.1 Proposed Product for Locally Manufacture (Human)

bs	*c¯ZKvi‡Ki bvg*	*JI‡ai bvg I †RvbwiK bvg*	*wb‡`kbv*	**Contra-indication & Side-effect**	**Status (New Molecule/ Existing)**	*Av‡e`bKvix c`Ë USFDA or MHRA Ref.*	*‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš*	*mfvi wm×vš*
01.	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	a) Aciclovir 5gm + Hydrocortisone 1gm/100gm Cream Aciclovir BP 5gm + Hydrocortisone BP1gm/100gm **Antiviral**	It is is indicated for the early treatment of recurrent herpes labialis (cold sores) to reduce the likelihood of ulcerative cold sores and to shorten the lesion healing time in adults and children (6 years of age and older).	**Contraindications:** None. **Side-effects:** The following most common adverse reactions (<1%) were local skin reactions: • Drying or flaking of the skin; burning or tingling, erythema; pigmentation changes; application site reactions including signs and symptoms of inflammation.	Aciclovir 5% Cream	USFDA	*Abxgv`b Kiv †h‡Z cv‡i|*	*Abxgv`b Kiv nj|*
		b) Mesalazine 1200mg Delayed ReleaseTablet Mesalazine USP 1200mg **Nonsteroidal Anti-inflamatory**	Treatment of mild to moderate ulcerative colitis and maintenance of remission.	**Contraindication:** Aminosalicylates should be avoided in salicylate hypersensitivity. **Side-effects:** Side effects of the aminosalicylates include diarrhoea, nausea, vomiting, abdominal pain, exacerbation of symptoms of colitis, headache, hypersensitivity, reactions (including rash & urticaria); side-effects that occur rarely include acute pancreatitis, Hepatititis, myocarditis, pericarditis, lung disorders (including eosinophillia and fibrosing alveolitis), peripheral neuropathy, blood disorders (including agranulocytosis, aplastic anaemia, leucopenia, methaemoglobinaemia, neutropenia, and thrombocytopenia), renal dysfunction (intestinal nephritis, nephrotic syndrome), myalgia, arthralgia, skin reactions (including lupus erythromatosus-like syndrome, Stevens-Johnson syndrome), alopecia.	400mg Tablet	BNF	*D"PgvÎvi †WvR c‡qvRb ‡bB weavq Av‡e`b bvgÄyb Kiv †h‡Z cv‡i|*	*D"PgvÎvi †WvR c‡qvRb ‡bB weavq Av‡e`b bvgÄyb Kiv nj|*

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	c) Vitamin C 500 mg + Vitamin E 30 IU + Cyanocobalamine 60mcg + Biotin 0.150 mg + Folic Acid 1 mg + Carbonyl Iron 150 mg + Elemental Copper 3 mg + Docusate Sodium (Sodium Dioctylsulfosuccinate) 50mg Tablet Vitamin C BP 500 mg + Dry Vitamin E Acetate 50% Solid diluted BP 60mg eq. to dl-Alpha Tocopheryl Acetate BP 30 IU + Cyanocobalamine 1% Solid Diluted BP 6mg eq. to Cyanocobalamine 60mcg + Biotin BP 0.150 mg + Folic Acid BP 1 mg + Carbonyl Iron Ph. Gr. 153.00 mg eq. to elemental Iron 150mg + Anhydrous Copper Sulfate BP 7.54mg eq. to elemental Copper 3 mg + Docusate Sodium (Sodium Dioctylsulfosuccinate) BP 50 mg **Multivitamin and Multimineral**	For the treatment of anaemia-Megaloblastic, macrocytic and iron-deficiency anemia, anemia of pregnancy and anemia occurring in a variety of malabsorption syndromes	**Contraindications:** This preparation is contraindicated in patients with a known hypersensitivity to any of the components of this product. Hemochromatosis and hemosiderosis are contraindications to iron therapy. **Side effects:** Constipation, dark or discolored stools; diarrhea, nausea, stomach upset, vomiting.	New		c‡qvRb ‡bB weavq Av‡e`b bvgÄyK Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyK Kiv nj
		d) Rivaroxaban 2.5mg Tablet Rivaroxaban INN 2.5mg **Anticoagulant**	It is used for the following in adults: • to prevent venous thromboembolism (VTE, the formation of blood clots in the veins) in patients who are undergoing surgery to replace a hip or knee; • to prevent stroke caused by a blood clot in the brain and systemic embolism (a blood clot in a blood vessel) in patients with non-valvular atrial fibrillation (irregular rapid contractions of the upper chambers of the heart); • to treat deep vein thrombosis	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Active clinically significant bleeding. Lesion or condition, if considered to be a significant risk for major bleeding. This may include current or recent gastrointestinal ulceration, presence of malignant neoplasms at high risk of bleeding, recent brain or spinal injury, recent brain, spinal or ophthalmic surgery, recent intracranial haemorrhage, known or suspected oesophageal varices, arteriovenous malformations, vascular aneurysms or major intraspinal or intracerebral vascular abnormalities. Concomitant treatment with any other anticoagulants e.g. unfractionated heparin (UFH), low molecular weight heparins	10mg, 15mg & 20mg Tablet	BNF-69 Page No. 158	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

			(DVT, a blood clot in a deep vein, usually in the leg) and pulmonary embolism (a clot in a blood vessel supplying the lungs), and to prevent DVT and pulmonary embolism from re-occuring. • to prevent atherothrombotic events (problems caused by blood clots and hardening of the arteries) after an acute coronary syndrome. Acute coronary syndrome is a group of conditions that includes unstable angina (a severe type of chest pain) and heart attack. It is used together with antiplatelet medicines, which prevent the blood from clotting.	(enoxaparin, dalteparin, etc.), heparin derivatives (fondaparinux, etc.), oral anticoagulants (warfarin, dabigatran etexilate, apixaban, etc.) except under the circumstances of switching therapy to or from Rivaroxaban or when UFH is given at doses necessary to maintain an open central venous or arterial catheter. Concomitant treatment of ACS with antiplatelet therapy in patients with a prior stroke or a transient ischaemic attack (TIA). Hepatic disease associated with coagulopathy and clinically relevant bleeding risk including cirrhotic patients with Child Pugh B and C. Pregnancy and breast feeding. **Side effects:** Due to the pharmacological mode of action, the use of Rivaroxaban may be associated with an increased risk of occult or overt bleeding from any tissue or organ which may result in post haemorrhagic anaemia. The signs, symptoms and severity (including fatal outcome) will vary according to the location and degree or extent of the bleeding and/or anaemia. In the clinical studies mucosal bleedings (i.e. epistaxis, gingival, gastrointestinal, genito urinary) and anaemia were seen more frequently during long term Rivaroxaban treatment compared with VKA treatment. Thus, in addition to adequate clinical surveillance, laboratory testing of haemoglobin/haematocrit could be of value to detect occult bleeding, as judged to be appropriate. The risk of bleedings may be increased in certain patient groups e.g. those patients with uncon¬trolled severe arterial hypertension and/or on concomitant treatment affecting haemostasis. Menstrual bleeding may be intensified and/or prolonged. Haemorrhagic complications may present as weakness, paleness, dizziness, headache or unexplained swelling, dyspnoea and unexplained shock. In some cases as a consequence of anaemia, symptoms of cardiac ischaemia like chest pain or angina pectoris have been observed. Known complications secondary to severe bleeding such as compartment syndrome and renal failure due to hypoperfusion have been reported for Rivaroxaban. Therefore, the possibility of haemorrhage is to be considered in evaluating the condition in any anticoagulated patient.				

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	e) Ulipristal Acetate 5mg Tablet Ulipristal Acetate INN 5mg **Preogeterone receptor Modulator**	It is indicated for pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Pregnancy and breastfeeding. Genital bleeding of unknown aetiology or for reasons other than uterine fibroids. Uterine, cervical, ovarian or breast cancer. **Side effects:** Nausea, abdominal pain, oedema, hot turbances, uterine hemmorages, endometrial thickening, ovarian cyst (including rupture), breast pain, pelvic pain, myalgia, acne, hyperhidrosis, less commonly dyspepsia, dry mouth, flatulence, constipation, epitaxis, anxiety, urinary inconsistence.	30mg Tablet	BNF	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		f) Aripiprazole 2mg Tablet Aripiprazole USP 2mg **Anti-Psychotic**	It is an atypical antipsychotic. The oral formulations are indicated for: Schizophrenia, Acute Treatment of Manic and Mixed Episodes associated with Bipolar I, Adjunctive Treatment of Major Depressive Disorder, Irritability Associated with Autistic Disorder, Treatment of Tourette's disorder.	**Contraindications:** Known hypersensitivity to Aripiprazole. **Side effects:** Adult patients with schizophrenia: akathisia Pediatric patients (13 to 17 years) with schizophrenia: extrapyramidal disorder, somnolence, and tremor Adult patients (monotherapy) with bipolar mania: akathisia, sedation, restlessness, tremor, and extrapyramidal disorder Adult patients (adjunctive therapy with lithium or valproate) with bipolar mania: akathisia, insomnia, and extrapyramidal disorder Pediatric patients (10 to 17 years) with bipolar mania: somnolence, extrapyramidal disorder, fatigue, nausea, akathisia, blurred vision, salivary hypersecretion, and dizziness Adult patients with major depressive disorder (adjunctive treatment to antidepressant therapy): akathisia, restlessness, insomnia, constipation, fatigue, and blurred vision. Pediatric patients (6 to 17 years) with autistic disorder: sedation, fatigue, vomiting, somnolence, tremor, pyrexia, drooling, decreased appetite, salivary hypersecretion, extrapyramidal disorder, and lethargy Adult patients with agitation associated with schizophrenia or bipolar mania: nausea.	5mg, 10mg, 15mg Tablet	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	g) Aripiprazole 100mg/100ml Oral Solution Aripiprazole USP 100mg/100ml **Anti-Psychotic**	It is an atypical antipsychotic. The oral formulations are indicated for: Schizophrenia, Acute Treatment of Manic and Mixed Episodes associated with Bipolar I, Adjunctive Treatment of Major Depressive Disorder, Irritability Associated with Autistic Disorder, Treatment of Tourette's disorder.	**Contraindications:** Known hypersensitivity to Aripiprazole. **Side effects:** Adult patients with schizophrenia: akathisia Pediatric patients (13 to 17 years) with schizophrenia: extrapyramidal disorder, somnolence, and tremor Adult patients (monotherapy) with bipolar mania: akathisia, sedation, restlessness, tremor, and extrapyramidal disorder Adult patients (adjunctive therapy with lithium or valproate) with bipolar mania: akathisia, insomnia, and extrapyramidal disorder Pediatric patients (10 to 17 years) with bipolar mania: somnolence, extrapyramidal disorder, fatigue, nausea, akathisia, blurred vision, salivary hypersecretion, and dizziness Adult patients with major depressive disorder (adjunctive treatment to antidepressant therapy): akathisia, restlessness, insomnia, constipation, fatigue, and blurred vision Pediatric patients (6 to 17 years) with autistic disorder: sedation, fatigue, vomiting, somnolence, tremor, pyrexia, drooling, decreased appetite, salivary hypersecretion, extrapyramidal disorder, and lethargy • Adult patients with agitation associated with schizophrenia or bipolar mania: nausea.	5mg, 10mg, 15mg Tablet	USFDA	Abyôv`b Kiv †h‡Z cv‡i	Abyôv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	h) Aripiprazole 9.75mg/1.3ml Injection Aripiprazole USP 9.75mg/1.3ml **Anti-Psychotic**	It is an atypical antipsychotic indicated as the injection is indicated for Agitation associated with schizophrenia or bipolar mania.	**Contraindications:** Known hypersensitivity to Aripiprazole. **Side effects:** Adult patients with schizophrenia: akathisia • Pediatric patients (13 to 17 years) with schizophrenia: extrapyramidal disorder, somnolence, and tremor • Adult patients (monotherapy) with bipolar mania: akathisia, sedation, restlessness, tremor, and extrapyramidal disorder • Adult patients (adjunctive therapy with lithium or valproate) with bipolar mania: akathisia, insomnia, and extrapyramidal disorder • Pediatric patients (10 to 17 years) with bipolar mania: somnolence, extrapyramidal disorder, fatigue, nausea, akathisia, blurred vision, salivary hypersecretion, and dizziness • Adult patients with major depressive disorder (adjunctive treatment to antidepressant therapy): akathisia, restlessness, insomnia, constipation, fatigue, and blurred vision • Pediatric patients (6 to 17 years) with autistic disorder: sedation, fatigue, vomiting, somnolence, tremor, pyrexia, drooling, decreased appetite, salivary hypersecretion, extrapyramidal disorder, and lethargy • Adult patients with agitation associated with schizophrenia or bipolar mania: nausea.	5mg, 10mg, 15mg Tablet	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	Jl‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	i) Lafutidine 5mg Tablet Lafutidine INN 5mg **H_2 Receptor Blocker**	- Gastric ulcers, duodenal ulcers and stomal ulcers. - Gastric mucosal lesions (erosion, hemorrhage, redness or edema) associated with acute gastritis and acute exacerbation of chronic gastritis. - Preanesthetic medication.	**Contraindications:** Patients with a history of drug hypersensitivity to any of the ingredients in the product. **Side effects:** Adverse reactions (including abnormal changes in labotaroty tests) were observed in 32 (2.5%) of the 1,287 patients evaluated at the time of approval. The main adverse reactions were constipation in 3 patients (0.2%). Abnormal changes in laboratory tests were observed in 22 patients.	New		c‡qvRbxq †idv‡iÝ †bB Ges ‡`‡k c‡qvRb ‡bB wea|q Av‡e`b bvgÄyÝ Kiv †h‡Z cv‡i|	c‡qvRbxq †idv‡iÝ †bB Ges ‡`‡k c‡qvRb ‡bB wea|q Av‡e`b bvgÄyÝ Kiv nj|
		j) Lafutidine 10mg Tablet Lafutidine INN 10mg **H_2 Receptor Blocker**	- Gastric ulcers, duodenal ulcers and stomal ulcers. - Gastric mucosal lesions (erosion, hemorrhage, redness or edema) associated with acute gastritis and acute exacerbation of chronic gastritis. - Preanesthetic medication.	**Contraindications:** Patients with a history of drug hypersensitivity to any of the ingredients in the product. **Side effects:** Adverse reactions (including abnormal changes in labotaroty tests) were observed in 32 (2.5%) of the 1,287 patients evaluated at the time of approval. The main adverse reactions were constipation in 3 patients (0.2%). Abnormal changes in laboratory tests were observed in 22 patients.	New		c‡qvRbxq †idv‡iÝ †bB Ges ‡`‡k c‡qvRb ‡bB wea|q Av‡e`b bvgÄyÝ Kiv †h‡Z cv‡i|	c‡qvRbxq †idv‡iÝ †bB Ges ‡`‡k c‡qvRb ‡bB wea|q Av‡e`b bvgÄyÝ Kiv nj|
		k) Macrogol (3350) 13.125gm + Sodium Bicarbonate 178.5mg + Sodium Chloride 350.7mg + Potassium Chloride 46.6mg/25ml Concentrated oral solution Macrogol (3350) BP 13.125gm + Sodium Bicarbonate BP 178.5mg + Sodium Chloride BP 350.7mg + Potassium Chloride BP 46.6mg/25ml **Laxative**	For the treatment of chronic constipation.	Contraindication: Intestinal perforation or obstruction due to structural or functional disorder of the gut wall, ileus, severe inflammatory conditions of the intestinal tract, such as Crohn's disease and ulcerative colitis and toxic megacolon. Hypersensitivity to the active ingredients or to any of the excipients. Side effects: Abdominal distension and pain, borborygmi and nausea, attributable to the expansion of the contents of the intestinal tract can occur. Mild diarrhoea which usually responds to dose reduction. Allergic reactions are a possibility.	Macrogol (3350) INN 13.125 gm + Sodium Chloride BP 350.7mg + Sodium Bicarbonate BP 178.5 mg + Potassium Chloride BP 46.6mg/Sachet powder for oral solution	BNF-67	Abjgv`b Kiv †h‡Z cv‡i|	Abjgv`b Kiv nj|

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	l) Paroxetine 7.5mg Capsule Paroxetine Mesylate INN 9.69mg eq. to Paroxetine 7.5mg **Antidepressant**	It is a selective serotonin reuptake inhibitor (SSRI) indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause (VMS) **Limitation of Use:** It is not indicated for the treatment of any psychiatric condition	**Contraindication:** • Concurrent use with monoamine oxidase inhibitors (MAOI) or use within 14 days of MAOI use • Use with thioridazine • Use with pimozide • Hypersensitivity to any ingredient in the final formulation • Pregnancy **Side effects:** The most common adverse reactions (≥ 2%) reported in clinical trials were: headache, fatigue, and nausea/vomiting.	10mg & 20mg Tablet	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		m) Ascorbic acid 1000mg + Elemental zinc 10mg Effervescent Tablet Ascorbic acid BP 1000mg + Zinc Sulfate Monohydrate USP 27.445mg eq. to Elemental zinc 10mg **Vitamin**	Treatment of Vitamin C & Zinc deficiency	**Contraindication:** This product must not be taken by persons known to be hypersensitive to any of its ingredients. Patients suffering from oxalate urolithiasis or oxaluria must not take this product. Patients suffering from severe renal insufficiency or renal failure must not take the product. **Side effects:** Gastrointestinal side effects like Diarrhea. Nausea, vomiting, abdominal pain, stomach discomfort etc. & Immune system Disorder like Allergic reaction, anaphylactic reaction, anaphylactic shock etc.	Ascorbic acid 1000mg Effervescent Tablet		‡idv‡iÝ Ges c‡qvRb †bB wea|q Av‡e`b bvgÄyb Kiv †h‡Z cv‡i	†idv‡iÝ †bB Ges c‡qvRb ‡bB wea|q Av‡e`b bvgÄyb Kiv nj
		n) Deflazacort 1mg Tablet Deflazacort INN 1mg **Glucocorticoid**	A wide range of conditions may sometimes need treatment with glucocorticoids. The indications include: Anaphylaxis, asthma, severe hypersensitivity reactions Rheumatoid arthritis, juvenile chronic arthritis, polymyalgia rheumatic Systemic lupus erythematosus, dermatomyositis, mixed connective tissue disease (other than systemic sclerosis), polyarteritis nodosa, sarcoidosis Pemphigus, bullous pemphigoid, pyoderma gangrenosum Minimal change nephrotic syndrome, acute interstitial nephritis Rheumatic carditis Ulcerative colitis, Crohn's disease Uveitis, optic neuritis Autoimmune haemolytic anaemia,	**Contraindication:** Systemic infection unless specific anti-infective therapy is employed. Hypersensitivity to deflazacort or any of the ingredients. Patients receiving live virus immunisation. **Side effects:** The incidence of predictable undesirable effects, including hypothalamic-pituitaryadrenal suppression correlates with the relative potency of the drug, dosage, timing of administration and the duration of treatment. **Endocrine/metabolic:** Suppression of the hypothalamic-pituitary-adrenal axis, growth suppression in infancy, childhood and adolescence, menstrual irregularity and amenorrhoea. Cushingoid facies, hirsutism, weight gain, impaired carbohydrate tolerance with increased requirement for anti-diabetic therapy. Negative protein and calcium	6mg Tablet		c‡qvRb †bB wea|q Av‡e`b bvgÄyb Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyb Kiv nj

			idiopathic thrombocytopenic purpura Acute and lymphatic leukaemia, malignant lymphoma, multiple myeloma Immune suppression in transplantation	balance. Increased appetite. **Anti-inflammatory and immunosuppressive effects** Increased susceptibility and severity of infections with suppression of clinical symptoms and signs, opportunistic infections, recurrence of dormant tuberculosis. **Musculoskeletal** Osteoporosis, vertebral and long bone fractures, avascular osteonecrosis, tendon rupture. Muscle wasting or myopathy (acute myopathy may be precipitated by nondepolarising muscle relaxants, negative nitrogen balance. **Fluid and electrolyte disturbance** Sodium and water retention with hypertension, oedema and heart failure, potassium loss, hypokalaemic alkalosis. **Neuropsychiatric** Headache, vertigo, psychological dependence, hypomania or depression, restlessness. Increased intra-cranial pressure with papilloedema in children (Pseudotumour cerebri), usually after treatment withdrawal. Aggravation of epilepsy. A wide range of psychiatric reactions including affective disorders (such as irritable, euphoric, depressed and labile mood, and suicidal thoughts), psychotic reactions (including mania, delusions, hallucinations, and aggravation of schizophrenia), behavioural disturbances, irritability, anxiety, sleep disturbances, and cognitive dysfunction including confusion and amnesia have been reported. Reactions are common and may occur in both adults and children. In adults, the frequency of severe reactions has been estimated to be 5-6%. Psychological effects have been reported on withdrawal of corticosteroids; the frequency is unknown. **Ophthalmic** Increased intra-ocular pressure, glaucoma, papilloedema, posterior subcapsular cataracts especially in children, corneal or scleral thinning, exacerbation of ophthalmic viral or fungal diseases. **Gastrointestinal** Dyspepsia, peptic ulceration with				

				perforation and haemorrhage, acute pancreatitis (especially in children), candidiasis. Nausea. **Dermatological** Impaired healing, skin atrophy, bruising, telangiectasia, striae, acne. **General** Hypersensitivity including anaphylaxis has been reported. Leucocytosis. Thromboembolism. Rare incidence of benign intracranial hypertension. **Withdrawal symptoms and signs** Too rapid a reduction of corticosteroid dosage following prolonged treatment can lead to acute adrenal insufficiency; hypotension and death (see Warnings and Precautions). A 'withdrawal syndrome' may also occur including fever, myalgia, arthralgia, rhinitis, conjunctivitis, painful itchy skin nodules and loss of weight. This may occur in patients even without evidence of adrenal insufficiency.				
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	o) Deflazacort 30mg Tablet Deflazacort INN 30mg **Glucocorticoid**	A wide range of conditions may sometimes need treatment with glucocorticoids. The indications include Anaphylaxis, asthma, severe hypersensitivity reactions Rheumatoid arthritis, juvenile chronic arthritis, polymyalgia rheumatica Systemic lupus erythematosus, dermatomyositis, mixed connective tissue disease (other than systemic sclerosis), polyarteritis nodosa, sarcoidosis Pemphigus, bullous pemphigoid, pyoderma gangrenosum Minimal change nephrotic syndrome, acute interstitial nephritis Rheumatic carditis Ulcerative colitis, Crohn's disease Uveitis, optic neuritis Autoimmune haemolytic anaemia, idiopathic thrombocytopenic purpura Acute and lymphatic leukaemia, malignant lymphoma, multiple myeloma Immune suppression in transplantation	Do	6mg Tablet		*c‡qvRb †bB wea‡q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |*	*c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyi Kiv nj |*

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	p) Vinpocetin 5mg + Piracetam 400mg Capsule Vinpocetin BP 5mg + Piracetam BP 400mg **Cerebral vasodilator + Central stimulant**	Psychic or neurological symptoms of cerebral circulatory disturbances of various origins (post-apoplectic, post-traumatic or sclerotic) such as impaired memory, mobility disorders, vertigos and headaches. Intermittent cerebrovascular insufficiency, vascular spasms, ischemic cerebral lesions, advanced cerebral arteriosclerosis. Cerebro-vascular diseas, degenerative cortical dementia (Alzheimer's disease), Protection of the nervous tissue in a brain hypoxia.	**Contraindication:** It is contraindicated in pregnancy. Piracetam is contraindicated in patients with severe renal insufficiency (creatinine clearance. < 20 ml/min), hepatic impairment and those under 1 years of age. **Side effects:** It appears to be safe for most people. No significant harmful effects were reported in a study of people with Alzheimer's disease treated with large doses of vinpocetine (60 mg per day) for one year. Vinpocetine can cause some side effects including stomach pain, nausea, sleep disturbances, headache, dizziness, nervousness, and flushing of the face. The side effects of Piracetam reported include nervousness, agitation, irritability, and anxiety and sleep disturbances. The incidence of these during clinical trials was (≤ 5%) and they were more often noted in the older patients taking > 2.4 gm daily. In the majority of cases, a dose reduction sufficed to make these symptoms disappear. Some patients may complain of fatigue or drowsiness, gastrointestinal problems, e.g. nausea, vomiting, diarrhoea and stomachache have also been reported but their incidence during clinical trials was ≤ 2%. Other symptoms e.g. vertigo, headache, trembling and sexual stimulation have occasionally been reported.	Vinpocetin 5mg Tablet 10mg/2ml Injection		c‡qvRb †bB wea|q Av‡e`b bvgÄyK iv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK iv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	q) Nebivolol 5mg + Hydrochlorthiazide 12.50mg Tablet Nebivolol Hydrochloride INN 5.45mg eq. to 5mg Nebivolol + Hydrochlorthiazide BP 12.50mg **Anti-hypertensive & Diuretic**	• Nebivolol is a cardiovascular drug belonging to the group of selective beta-blocking agents (i.e. with a selective action on the cardiovascular system). It prevents increased heart rate and controls heart pumping strength. It also widens blood vessels, which helps to lower your blood pressure. • Hydrochlorothiazide is a diuretic that acts by increasing the amount of urine you produce. It is a one-tablet combination of nebivolol and hydrochlorothiazide and is used for the treatment of raised blood pressure (hypertension). It is used instead of the two separate products for those patients who are already taking them together.	**Contraindication:** -Hypersensitivity to the active substances or to any of the excipients. -Hypersensitivity to other sulphonamide-derived substances (since hydrochlorothiazide is a sulphonamide-derived medicinal product). - Liver insufficiency or liver function impairment. - Anuria, severe renal insufficiency (creatinine clearance < 30 ml/min.). - Acute heart failure, cardiogenic shock or episodes of heart failure decompensation requiring i.v. inotropic therapy. - Sick sinus syndrome, including sino-atrial block. - Second and third degree atrioventricular block (without a pacemaker). - Bradycardia (heart rate < 60 bpm prior to start therapy). - Hypotension (systolic blood pressure < 90 mmHg). - Severe peripheral circulatory disturbances. - History of bronchospasm and bronchial asthma. - Untreated phaeochromocytoma. - Metabolic acidosis. - Refractory hypokalaemia, hypercalcaemia, hyponatraemia and symptomatic hyperuricaemia **Side Effects:** The following side effects have been reported with nebivolol: Common side effects (affecting more than 1 person in every 100 treated but fewer than 1 person in every 10 treated): headache, dizziness, tiredness, an unusual burning, pricking, tickling, or tingling sensation, diarrhea, constipation, nausea, shortness of breath, swollen hands or feet. Uncommon side effects (affecting more than 1 person in every 1,000 treated, but fewer than 1 person in every 100 treated): slow heartbeat or other heart complaints, low blood pressure, cramp-like leg pains on walking, abnormal vision, impotence, feelings of depression, digestive difficulties, gas in stomach or bowel, vomiting, skin rash, itchiness, breathlessness such as in asthma, due to sudden cramps in the muscles around the airways (bronchospasm), nightmares. Very rare side effects (affecting fewer than 1 person in every 10,000 treated): fainting, worsening of psoriasis (a skin disease characterised by scaly pink patches).	Nebivolol 5mg & 2.5mg Tablet		‡idv‡iÝ Ges c‡qvRb †bB wea|q Av‡e`b bvgÄyÝ Kiv †h‡Z cv‡i |	†idv‡iÝ Ges c‡qvRb ‡bB wea|q Av‡e`b bvgÄyÝ Kiv nj |

				The following side effects have been reported only in some isolated cases: - whole-body allergic reactions, with generalised skin eruption (hypersensitivity reactions); rapid-onset swelling, especially around the lips, eyes, or of the tongue with possible sudden difficulty breathing (angioedema). The following side effects have been reported with hydrochlorothiazide: Allergic reactions - whole-body allergic reaction (anaphylactic reaction) Heart and circulation - heart rhythm disturbances, palpitations - changes in the electrocardiogram - sudden fainting when standing upright, formation of blood clots in veins (thrombosis) and embolism, circulatory collapse (shock) Blood - changes in the number of blood cells, such as: decreased white blood cells, decreased blood platelets, decreased red blood cells; impaired production of new blood cells by the bone marrow - altered levels of body fluids (dehydration) and blood chemicals, in particular decreased potassium, decreased sodium, decreased magnesium, decreased chlorine and increased calcium - increased uric acid levels, gout, increased blood glucose, diabetes, metabolic alkalosis (a disorder of metabolism), increased blood cholesterol and/or triglycerides Stomach and gut - lack of appetite, dry mouth, nausea, vomiting, stomach discomfort, abdominal pain, diarrhoea, fewer bowel movements (constipation), absence of bowel movements (ileus paralytic), flatulence - inflammation of the glands that produce saliva, inflammation of the pancreas, increased blood amylase level (a pancreatic enzyme) - yellowing of the skin (jaundice), inflammation of the gall bladder Chest - respiratory distress, lung inflammation (pneumonitis), formation of fibrous tissue in the lungs (interstitial lung disease), fluid accumulation in the lung (pulmonary oedema) Nervous system - vertigo (spinning sensation) - convulsions, depressed level of consciousness, coma, headache, dizziness - apathy, confusional state, depression, nervousness, restlessness, sleep disturbances - unusual burning, pricking, tickling, or tingling skin sensations - muscle weakness (paresis) Skin and hair				

				- itchiness, purple spots/blotches on the skin (purpura), hives (urticaria), increased sensitivity of your skin to sunlight, rash, facial rash and/or patchy redness that can cause scarring (cutaneous lupus erythematosus), inflammation of blood vessels with consequent death of tissue (vasculitis necrotising), peeling, redness, loosening, and blistering of the skin (toxic epidermal necrolysis) Eyes and ears - yellow vision, blurred vision, worsening of myopia, decreased tear production Joint and muscles - muscle spasm, muscle pain Urinary - Kidney dysfunction, acute kidney failure (reduced urine production and build-up of fluid and wastes in your body), inflammation of the connective tissue within the kidneys (interstitial nephritis), sugar in the urine. Sexual - Erection disturbances General/Other - General weakness, tiredness, fever, thirst				
		r) Sodium Ascorbate 360mg + Ascorbic Acid 180mg Chewable Tablet Sodium Ascorbate BP 360mg + Ascorbic Acid BP 180mg **Vitamin**	Vitamin C Therapy is essential in scurvy, but less florid manifestations of vitamin C deficiency are commonly found, especially in the elderly. It is rarely necessary to prescribe more than 100mg daily except early in the treatment of scurvy.	**Contraindication:** Ingestion of megadose (more than 100mg daily) of vitamin C during pregnancy has resulted in scurvy in neonates. Vitamin C in mega-doses has been contraindicated for patients with hyperoxaluria. **Side Effects:** Vitamin C has little toxicity and only mega-doses of Vitamin C may cause diarrhea, abdominal bloating, iron over-absorption that is harmful in patients with sideroblastic anemia, and haemochromatosis; hyperoxaluria, hyperuricosuria, and hemolysis in patients with glucose-6 phosphate dehydrogenase deficiency.	250mg Chewable Tablet, 1000mg Tablet		*Abyjgv`b Kiv †h‡Z cv‡i |*	*Abyjgv`b Kiv nj |*

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Square Pharmaceuticals Ltd., Pabna Unit, Salgaria, Pabna	s) Oseltamivir 30mg/5ml Oral Suspension Oseltamivir Phosphate BP 472.80mg Eq. to Oseltamivir 360mg/60ml Oral Suspension **Antiviral**	It is an influenza neuraminidase inhibitor indicated for: Treatment of acute, uncomplicated influenza in patients 2 weeks of age and older who have been symptomatic for no more than 2 days. Prophylaxis of influenza in patients 1 year and older. Important Limitations of Use: Efficacy not established in patients who begin therapy after 48 hours of symptoms. Not a substitute for annual influenza vaccination. No evidence of efficacy for illness from agents other than influenza viruses types A and B. Consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use.	**Contraindications:** Patients with known serious hypersensitivity to oseltamivir or any of the components of the product. **Side-effects:** Most common adverse reactions (>1% and more common than with placebo): Treatment studies – Nausea, vomiting Prophylaxis studies – Nausea, vomiting, diarrhea, abdominal pain	45mg & 75mg Capsule 60 mg/5ml Powder for suspension	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
02	**Square Pharmaceuticals Ltd., Dhaka Unit, Gazipur**	a) Aciclovir 800mg Dispersible Tablet Aciclovir BP 800mg **Anti-Viral**	Treatment of herpes zoster infections. Treatment of varicella (chickenpox) infections.	**Contraindications:** It is contraindicated in patients known to be hypersensitive to aciclovir, valaciclovir or any of the excipients. **Side effects:** Common side effects are Headache, dizziness, nausea, vomiting, diarrhea, abdominal apins, pruritus, rashes, fatigue and fever.	200mg & 400mg Tablet, 200mg/5ml Suspension	MHRA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		b) Bromfenac Sodium free acid 0.7mg/ml Ophthalmic solution Bromfenac Sodium Sesquihydrate INN 0.805mg eq. to Bromfenac free acid 0.7mg/ml **Ocular NSAID**	It is a nonsteroidal anti-inflammatory drug (NSAID) indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.	**Contra-indication:** None **Side effects:** **Clinical Trial Experience:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. The most commonly reported adverse reactions following use of it following cataract surgery include: anterior chamber inflammation, foreign body sensation, eye pain, photophobia, and vision blurred. These reactions were reported in 3 to 8% of patients.	0.9% Eye Drops	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Square Pharmaceuticals Ltd., Dhaka Unit, Gazipur	c) Povidone Iodine 2.5gm/100gm Topical Spray Povidone Iodine BP 2.5gm/100gm (2.5% Topical Spray) **Antiseptic Spray**	Treatment of prevention of infection in minor cuts and abrasions, minor surgical procedures, small areas of burns & leg ulcers. Treatment of fungal & bacterial skin infection.	**Contraindication:** Allergy to iodine; Deep wounds which are weeping; children under 2 years of age. **Side effects:** Following side effects may occur after prolonged use of this spray on severe burns and large areas of broken skin. - Decreased kidney function - Interference with thyroid function - Increased acid levels in the blood (metabolic acidosis)	2.5gm/100ml Spray		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj	
		d) Triamcinolone Acetate 0.0147gm/100gm Topical Spray Triamcinolone Acetate BP 0.0147gm/100gm **Corticosteroids**	Indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.	**Contraindication:** Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations. **Side effects:** Allergic reactions to Triamcinolone may include: hives; difficulty in brreathing; swelling of face, lips, tongue, or throat. If Triamcinolone is absorbed to a larger extent through skin or gums, followings may occur: blurred vision, or seeing halos around lights; uneven heartbeats; mood changes; sleep problems (insomnia); weight gain, puffiness in your face; feeling tired. Less serious side effects may include: skin redness, burning, itching, or peeling; thinning of skin; or blistering in skin; or stretch marks.	0.1% Cream/ Ointment/Oral Paste		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj	
		e) Methyl Nicotinate 1.60gm + 2-Hydroxyethyl Salicylate 5gm + Methyl Salicylate 1gm + Ethyl Salicylate 5gm/100gm Topical Spray Methyl Nicotinate BP 1.60gm + 2-Hydroxyethyl Salicylate BP 5gm + Methyl Salicylate BP 1gm + Ethyl Salicylate Pharma grade 5gm/100gm **Topical Anti-inflammatory**	This medicine is used to treat muscular aches, sprains, and strains. It contains a mixture of ingredients that have warming, pain-relieving, and anti-inflammatory effects that can help treat these types of conditions.	**Contraindication:** - allergy to any of the ingredients - allergy to pain relievers such as aspirin, ibuprofen or other anti-inflammatories - Children under 5 years old - on broken skin, eyes or other senditive areas of skin **Side-effects:** The following side-effects have been associated with people having this medicine. Stop using this medicine if you get an irritation or any of the following side-effects include skin burns, blisters, temporary skin reactions such as redness, burning, or rashes	New		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj	

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Square Pharmaceuticals Ltd., Dhaka Unit, Gazipur	f) Benzocaine 18gm + Tetracaine Hydrochloride 2gm/100gm Oral Topical Spray Benzocaine BP 18gm + Tetracaine Hydrochloride BP 2gm/100gm **Topical Anagesic**	It is indicated o minimize pain in oral mucosal tissues and reduce the pharyngeal (gag) reflex associated with the placement into the oral cavity of impression trays, x-ray films, x-ray plate holders.	**Contra-indication:** Hypersensitivity to Benzocaine or Tetracaine HCl **Side-effects:** Common adverse reaction caused by local anesthetics is contact dermatitis characterized by erythema andpruritus that may progress to vesiculation and oozing. If rash, urticaria, edema or other manifestations of allergy develop during use, the drug shourd be discontinued.	New		*Abyjgv`b Kiv †h‡Z cv‡i |*	*Abyjgv`b Kiv nj |*
		g) Diclofenac Diethylamine 1.16gm/100gmTopical Spray Diclofenac Diethylamine BP 1.16gm/100gm Topical Spray **Topical NSAID**	It can be used for relief from back pain, joint pain, knee, neck & shoulder pain. It is ideal in minor sports injuries & mucle sprains. It can be applied to pain site & no message is required.	**Contra-indication:** Hypersensitivity to Diclofenac **Side-effects:** Transient skin rashes	New		*Abyjgv`b Kiv †h‡Z cv‡i |*	*Abyjgv`b Kiv nj |*
		h) Olopatadine Hydrochloride 0.7% Opthalmic Solution Olopatadine Hydrochloride USP 7.76 mg eq. to 7mg Olopatadine/ml **Antiallergic**	Temporary relief of itching caused by allergic conjunctivitis (ophthalmic); relief of symptoms of seasonal allergic rhinitis (intranasal).	Contra-indication: Hypersensitivity to Olopatadine Hydrochloride or any component of the preparation. Side-effects: CNS: Asthenia (5% or less); headache (4%); fatigue, somnolence (1%); depression or worsening of depression. GI: Bitter taste (13%); nausea, taste perversion. Ophthalmic: Blurred vision; burning, dry eye, foreign body sensation, hyperemia, keratitis, lid edema, pruritus, stinging (5% or less). Respiratory: Upper respiratory tract infection (3%); pharyngolaryngeal pain (2%); cough, nasopharyngitis (1%). Special Senses: Epistaxis (25%); nasal ulceration (10%); postnasal drip (2%); dry mouth, throat irritation (1%); rhinitis, sinusitis. Miscellaneous: CPK elevation, influenza, pyrexia, rash, UTI (1%); dysgeusia, flu syndrome, weight increase.	1% and 0.2% Eye Drops 0.6% Nasal Spray	USFDA	*c‡qvRb †bB wea‡q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |*	*c‡qvRb †bB wea‡q Av‡e`b bvgÄyi Kiv nj |*

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
03	**Square Pharmaceuticals Ltd., Chemicals Division, BSCIC I/A, Pabna**	a) Ticarcillin 750mg + Clavulanic Acid 50mg Injection Sterile Mixture of Ticarcillin Disodium and Clavulanic Acid (15 :1) for Injection USP 1000mg containing Ticarcillin 750mg + Clavulanic Acid 50mg/Vial **Antibiotic (Carboxypenicillin)**	To reduce the development of drug-resistant bacteria and maintain the effectiveness of Ticarcillin 3000mg + Clavulanic Acid 200mg/Vial Injection and other antibacterial drugs. It should be used only to treat infections that are proven or strongly suspected to be caused by bacteria. It is a combination of a β-lactam antibacterial and a β-lactamase inhibitor indicated for the treatment of the following infections due to designated susceptible bacteria: Septicemia, Lower respiratory infections, Bone and joint infections, Skin and skin structure infections, Urinary tract infections, Gynecologic infections, Intra-abdominal infections.	**Contraindication:** History of a serious hypersensitivity reaction (anaphylaxis or Stevens-Johnson syndrome) to TIMENTIN or to other β-lactams (e.g., penicillins and cephalosporins). **Side effects:** Most common adverse reactions (≥1%) are rash, nausea, diarrhea, and phlebitis at injection site.	New		c‡qvRb †bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb †bB wea|q Av‡e`b bvgÄyi Kiv nj |
		b) Ticarcillin 1500mg + Clavulanic Acid 100mg/Vial Injection Sterile Mixture of Ticarcillin Disodium and Clavulanic Acid (15 :1) for Injection USP 2000mg containing Ticarcillin 1500mg + Clavulanic Acid 100mg/Vial **Antibiotic (Carboxypenicillin)**	To reduce the development of drug-resistant bacteria and maintain the effectiveness of Ticarcillin 3000mg + Clavulanic Acid 200mg/Vial Injection and other antibacterial drugs. It should be used only to treat infections that are proven or strongly suspected to be caused by bacteria. It is a combination of a β-lactam antibacterial and a β-lactamase inhibitor indicated for the treatment of the following infections due to designated susceptible bacteria: Septicemia, Lower respiratory infections, Bone and joint infections, Skin and skin structure infections, Urinary tract infections, Gynecologic infections, Intra-abdominal infections.	**Contraindication:** History of a serious hypersensitivity reaction (anaphylaxis or Stevens-Johnson syndrome) to TIMENTIN or to other β-lactams (e.g., penicillins and cephalosporins). **Side effects:** Most common adverse reactions (≥1%) are rash, nausea, diarrhea, and phlebitis at injection site.	New		wkï‡`i Rb¨ c‡qvRbxqZv we‡ePbv K‡i Abyôvb`v Kiv †h‡Z cv‡i |	wkï‡`i Rb¨ c‡qvRbxqZv we‡ePbv K‡i Abyôvb`v Kiv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Square Pharmaceuticals Ltd., Chemicals Division, BSCIC I/A, Pabna	c) Ticarcillin 3000mg + Clavulanic Acid 200mg/Vial Injection Sterile Mixture of Ticarcillin Disodium and Clavulanic Acid (15 :1) for Injection USP 4000mg containing Ticarcillin 3000mg + Clavulanic Acid 200mg/Vial **Antibiotic (Carboxypenicillin)**	To reduce the development of drug-resistant bacteria and maintain the effectiveness of Ticarcillin 3000mg + Clavulanic Acid 200mg/Vial Injection and other antibacterial drugs. It should be used only to treat infections that are proven or strongly suspected to be caused by bacteria. It is a combination of a β-lactam antibacterial and a β-lactamase inhibitor indicated for the treatment of the following infections due to designated susceptible bacteria: Septicemia, Lower respiratory infections, Bone and joint infections, Skin and skin structure infections, Urinary tract infections, Gynecologic infections, Intra-abdominal infections.	**Contraindication:** History of a serious hypersensitivity reaction (anaphylaxis or Stevens-Johnson syndrome) to TIMENTIN or to other β-lactams (e.g., penicillins and cephalosporins). **Side effects:** Most common adverse reactions (≥1%) are rash, nausea, diarrhea, and phlebitis at injection site.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
04	Veritas Pharmaceuticals Ltd.	a) Canagliflozin 50 mg + Metformin HCl 500 mg Tablet Canagliflozin INN 50 mg + Metformin HCl BP 500 mg **Antidiabetic**	It is a sodium-glucose co-transporter 2 (SGLT2) inhibitor and biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing metformin or canagliflozin or in patients already being treated with both canagliflozin and metformin **Limitation of Use:** Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	**Contraindications:** ▪ Renal impairment, ESRD, or on dialysis ▪ Metabolic acidosis, including diabetic ketoacidosis ▪ History of serious hypersensitivity reaction to Canagliflozin or Metformin hydrochloride **Side effects:** Most common adverse reactions associated with canagliflozin (5% or greater incidence): female genital mycotic infections, urinary tract infection, and increased urination. Most common adverse reactions associated with metformin (5% or greater incidence) are diarrhea, nausea, vomiting, flatulence, asthenia, indigestion, abdominal discomfort, and headache	Canagliflozin 100mg Tablet	USFDA	c‡qvRb †bB wea‡q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb †bB wea‡q Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Veritas Pharmaceuticals Ltd.	b) Canagliflozin 150 mg + Metformin HCl 500 mg Tablet Canagliflozin INN 150 mg + Metformin HCl BP 500 mg **Antidiabetic**	It is a sodium-glucose co-transporter 2 (SGLT2) inhibitor and biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing metformin or canagliflozin or in patients already being treated with both canagliflozin and metformin **Limitation of Use:** Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	**Contraindications:** ▪ Renal impairment, ESRD, or on dialysis ▪ Metabolic acidosis, including diabetic ketoacidosis ▪ History of serious hypersensitivity reaction to Canagliflozin or Metformin hydrochloride **Side effects:** ▪ Most common adverse reactions associated with canagliflozin (5% or greater incidence): female genital mycotic infections, urinary tract infection, and increased urination. ▪ Most common adverse reactions associated with metformin (5% or greater incidence) are diarrhea, nausea, vomiting, flatulence, asthenia, indigestion, abdominal discomfort, and headache.	Canagliflozin 100mg Tablet	USFDA	c‡qvRb †bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb †bB wea|q Av‡e`b bvgÄyi Kiv nj |
		c) Tedizolid Phosphate 200 mg Tablet Tedizolid Phosphate INN 200mg **Antibacterial**	It is an oxazolidinone-class antibacterial drug indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria. To reduce the development of drug-resistant bacteria and maintain the effectiveness of it and other antibacterial drugs, It should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.	Contraindications: None Side effects: The most common adverse reactions occurring in ≥2% of Patients: Nausea, diarrhea, vomiting, dizziness and headache	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
05	Incepta Pharmaceuticals Limited	a) Doxofylline 200mg Tablet Doxofylline In House 200mg **Bronchodilator**	Treatment of bronchial asthma and pulmonary disease with spastic bronchial component	**Contraindications:** Individuals who have shown hypersensitivity to Doxofylline and its components. Patients with acute myocardial infarction and hypotension. **Side Effects:** After xanthine administration, nausea, vomiting, epigastric pain, cephalalgia, irritability, insomnia, tachycardia, extrasystole, tachypnea and occasionally, hyperglycemia and albuminuria, may occur. If a potential oral overdose is established, the patient may present with severe arrhythmias and seizure; these symptoms could be the 1st sign of intoxication. Adverse reactions may cause the withdrawal from treatment; a lower dose rechallenge may start only after the advice of a physician	400mg Tablet and 100mg/5ml Syrup		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		b) Memantine HCl 14 mg + Donepezil HCl 10mg Extended Release Capsule Memantine HCl USP Extended Release 14mg + Donepezil HCl USP 10mg **CNS Agent**	It is indicated for the treatment of moderate to severe dementia of the Alzheimer's type in patients stabilized on: memantine hydrochloride (10mg twice daily or 28mg extended-release once daily) and donepezil hydrochloride 10mg memantine hydrochloride (5mg twice daily or 14mg extended-release once daily) and donepezil hydrochloride 10 mg (in patients with severe renal impairment).	**Contraindications:** It is contraindicated in patients with known hypersensitivity to Memantine HCl and Donepezil HCl, Piperidine derivatives, or to any excipients used in the formulation **Side Effects:** The most common adverse reactions occurring at a frequency of at least 5% and greater than placebo with memantine hydrochloride extended release 28 mg/day were headache, diarrhea, and dizziness. The most common adverse reactions occurring at a frequency of at least 5% in patients receiving donepezil and at twice or more the placebo rate, include diarrhea, anorexia, vomiting, nausea, and ecchymosis	Memantine 5mg and 10mg Tablet	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	c) Memantine HCl 28mg + Donepezil HCl 10mg Extended Release Capsule Memantine HCl USP Extended Release 28mg + Donepezil HCl USP 10mg **Acetylcholine esterase Inhibitor**	It is indicated for the treatment of moderate to severe dementia of the Alzheimer's type in patients stabilized on: memantine hydrochloride (10mg twice daily or 28mg extended-release once daily) and donepezil hydrochloride 10mg memantine hydrochloride (5mg twice daily or 14mg extended-release once daily) and donepezil hydrochloride 10 mg (in patients with severe renal impairment).	**Contraindications:** It is contraindicated in patients with known hypersensitivity to Memantine HCl and Donepezil HCl, Piperidine derivatives, or to any excipients used in the formulation **Side Effects:** The most common adverse reactions occurring at a frequency of at least 5% and greater than placebo with memantine hydrochloride extended release 28 mg/day were headache, diarrhea, and dizziness. The most common adverse reactions occurring at a frequency of at least 5% in patients receiving donepezil and at twice or more the placebo rate, include diarrhea, anorexia, vomiting, nausea, and ecchymosis.	Memantine 5mg and 10mg Tablet	USFDA	c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv nj
		d) Cromolyn Sodium 100mg/5ml Oral solution Cromolyn Sodium USP 100mg/5ml **Mast cell stabilizer**	Cromolyn Sodium Oral Solution (Concentrate) 100 mg/5 mL is indicated in the management of patients with Mastocytosis. Use of this product has been associated with improvement in diarrhea, flushing, headaches, vomiting, urticaria, abdominal pain, nausea, and itching in some patients.	**Contraindications:** Cromolyn Sodium Oral Solution (Concentrate) 100 mg/5 mL is contraindicated in those patients who have shown hypersensitivity to Cromolyn Sodium. **Side Effects:** Most of the adverse events reported in mastocytosis patients have been transient and could represent symptoms of the disease. The most frequently reported adverse events in mastocytosis patients who have received Cromolyn Sodium Oral Solution (Concentrate) 100 mg/5 mL during clinical studies were headache and diarrhea, each of which occurred in 4 of the 87 patients. Pruritus, nausea, and myalgia were each reported in 3 patients and abdominal pain, rash, and irritability in 2 patients each. One report of malaise was also recorded. Other Adverse Events: Additional adverse events have been reported during studies in other clinical conditions and from worldwide postmarketing experience. In most cases the available information is incomplete and attribution to the drug cannot be determined. The majority of these reports involve the gastrointestinal system and include: diarrhea, nausea,	New	USFDA	c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv nj

				abdominal pain, constipation, dyspepsia, flatulence, glossitis, stomatitis, vomiting, dysphagia, esophagospasm. Other less commonly reported events (the majority representing only a single report) include the following: Skin: pruritus, rash, urticaria/angioedema, erythema/burning, photosensitivity. Musculoskeletal: arthralgia, myalgia, stiffness/weakness of legs Neurologic: headache, dizziness, hypoesthesia, paresthesia, migraine, convulsions, flushing Psychiatric: psychosis, anxiety, depression, hallucinations, behavior change, insomnia, nervousness Heart Rate: tachycardia, premature ventricular contractions (PVCs), palpitations Respiratory: pharyngitis, dyspnea Miscellaneous: fatigue, edema, unpleasant taste, chest pain, postprandial lightheadedness and lethargy, dysuria, urinary frequency, purpura, hepatic function test abnormal, polycythemia, neutropenia, pancytopenia, tinnitus, lupus erythematosus (LE) syndrome.				
	Incepta Pharmaceuticals Limited	e) Cromolyn Sodium 20mg/2ml Nebulizer solution Cromolyn Sodium USP 20mg/2ml **Mast cell stabilizer**	Cromolyn Sodium is a prophylactic agent indicated in the management of patients with bronchial asthma. In patients whose symptoms are sufficiently frequent to require a continuous program of medication, It is given by inhalation on a regular daily basis. The effect of It is usually evident after several weeks of treatment, although some patients show an almost immediate response. In patients who develop acute bronchoconstriction in response to exposure to exercise, toluene diisocyanate, environmental pollutants, etc., Cromolyn Sodium should be given shortly before exposure to the precipitating factor.	**Contraindications:** Cromolyn Sodium is contraindicated in those patients who have shown hypersensitivity to cromolyn sodium **Side Effects:** The following adverse reactions have been associated with cromolyn sodium. **Nebulizer Solution**: cough, nasal congestion, nausea, sneezing, and wheezing. Other reactions have been reported in clinical trials; however, a causal relationship could not be established: drowsiness, nasal itching, nose bleed, nose burning, serum sickness, and stomachache.	New	USFDA	*c‡qvRb ‡bB wea‡q Av‡e`b bvgÄÿ K i‡v †h‡Z cv‡i |*	*c‡qvRb ‡bB wea‡q Av‡e`b bvgÄÿ K i‡v n j |*

bs	c¯ZKvi‡Ki bvg	Jl‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	f) Dapagliflozin 5mg + Metformin HCl 500mg Extended Release Tablet Dapagliflozin Propanediol monohydrate In House 6.15mg eq. to 5mg Dapagliflozin + Metformin HCl BP 500mg **Antidiabetic**	It is a combination of dapagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor, and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate. **Limitation of use:** Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	**Contraindication:** Moderate to severe renal impairment. History of serious hypersensitivity to dapagliflozin or hypersensitivity to metformin hydrochloride. Metabolic acidosis, including diabetic ketoacidosis. **Side Effects:** The most common adverse reactions associated with Dapagliflozin 5mg + Metformin HCl 500mg Extended Release Tablet (5% or greater incidence) were female genital mycotic infection, nasopharyngitis, urinary tract infection, diarrhea, and headache. Adverse reactions reported in >5% of patients treated with metformin extended-release and more commonly than in patients treated with placebo are: diarrhea and nausea/vomiting.	Dapagliflozin 5mg Tablet Metformin HCl 500mg ER Tablet	USFDA	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyÝ Ki‡v †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyÝ Ki‡v nj	
		g) Dapagliflozin 5mg + Metformin HCl 1000mg Extended Release Tablet Dapagliflozin Propanediol monohydrate In House 6.15mg eq. to 5mg Dapagliflozin + Metformin HCl BP 1000mg **Antidiabetic**	Do	Do	Dapagliflozin 5mg Tablet Metformin HCl 1000mg ER Tablet	USFDA	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyÝ Ki‡v †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyÝ Ki‡v nj	
		h) Dapagliflozin 10mg + Metformin HCl 500mg Extended Release Tablet Dapagliflozin Propanediol monohydrate In House 12.30mg eq. to 10mg Dapagliflozin + Metformin HCl BP 500mg **Antidiabertic**	Do	Do	Dapagliflozin 5mg Tablet Metformin HCl 500mg ER Tablet	USFDA	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyÝ Ki‡v †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyÝ Ki‡v nj	

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	i) Dapagliflozin 10mg + Metformin HCl 1000mg Extended Release Tablet Dapagliflozin Propanediol monohydrate In House 12.30mg eq. to 10mg Dapagliflozin + Metformin HCl BP 1000mg **Antidiabertic**	Do	Do	Dapagliflozin 5mg Tablet Metformin HCl 1000mg ER Tablet	USFDA	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv nj
		j) Ombitasvir 12.50mg + Paritaprevir 75mg + Ritonavir 50mg Tablet (Two) and Dasabuvir 250mg Tablet (Two); Co-packaged for Oral use Ombitasvir In House 12.50mg + Paritaprevir In House 75mg + Ritonavir BP 50mg; Dasabuvir In House 250mg **Antiviral**	Ombitasvir, Paritaprevir, Ritonavir combination & Dasabuvir with or without Ribavirin is indicated for the treatment of patients with genotype 1 chronic hepatitis C virus (HCV) infection including those with compensated cirrhosis. It includes ombitasvir, a hepatitis C virus NS5A inhibitor, paritaprevir, a hepatitis C virus NS3/4A protease inhibitor, ritonavir, a CYP3A inhibitor and dasabuvir, a hepatitis C virus non-nucleoside NS5B palm polymerase inhibitor. **Limitation of Use:** Ombitasvir, Paritaprevir, Ritonavir combination & Dasabuvir is not recommended for use in patients with decompensated liver disease.	**Contraindications:** If this combination drug is administered with ribavirin, the contraindications to ribavirin also apply to this combination regimen. Patients with severe hepatic impairment. Co-administration with drugs that are: highly dependent on CYP3A forclearance; strong inducers of CYP3A and CYP2C8; and strong inhibitors of CYP2C8. Known hypersensitivity to ritonavir (e.g. toxic epidermal necrolysis, Stevens Johnson syndrome) **Side Effects:** In subjects receiving this combination drug with ribavirin, the most commonly reported adverse reactions (greater than 10% of subjects) were fatigue, nausea, Pruritus, other skin reactions, insomnia and asthenia. In subjects receiving this combination drug without ribavirin, the most commonly reported adverse reactions (greater than or equal to 5% of subjects) were nausea, pruritus and insomnia.	New	USFDA	`ßvwU c‡`i Rb¨ c„_K c„_K †ivwR‡÷kb MnY Ki‡Z n‡e GB k‡Z K¬vc¨vK Abyôgv`b Kiv †h‡Z cv‡i	`ßvwU c‡`i Rb¨ c„_K c„_K †ivwR‡÷kb MnY Ki‡Z n‡e GB k‡Z K¬vc¨vK Abyôgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
		k) Ceftolozane 1gm + Tazobactam 0.5gm/Vial Injection Ceftolozane Sulphate and Tazobactam Sodium In House 2.7920gm containing Ceftolozane In House 1.0gm + Tazobactam In House 0.5gm/Vial **Antibiotic (Cephalosporin)**	Ceftolozane/Tazobactam for Injection is indicated for the treatment of patients 18 years or older with the following infections caused by designated susceptible microorganisms. **Complicated Intra-abdominal Infections**: Ceftolozane/ Tazobactam used in combination with metronidazole are indicated for the treatment of complicated intra-abdominal infections (cIAI) caused by the following Gram-negative and Gram-positive microorganisms: Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Bacteroides fragilis, Streptococcus anginosus, Streptococcus constellatus, and Streptococcus salivarius. **Complicated Urinary Tract Infections, including Pyelonephritis:** Ceftolozane/ Tazobactam is indicated for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following Gram-negative microorganisms: Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, and Pseudomonas aeruginosa. **Usage:** To reduce the development of drug-resistant bacteria and maintain the effectiveness of Ceftolozane/Tazobactam and other antibacterial drugs, Ceftolozane/Tazobactam should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy	**Contraindications:** CEFTOLOZANE/TAZOBACTAM is contraindicated in patients with known serious hypersensitivity to ceftolozane/tazobactam, piperacillin/tazobactam, or other members of the beta-lactam class. **Side Effects:** The following serious reactions are described in greater detail in the Warnings and Precautions section: • Hypersensitivity reactions • Clostridium difficile-associated diarrhea	New	USFDA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj

bs	c¯ZKvi‡Ki bvg		JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	l)	Suvorexant 5 mg Tablet Suvorexant In House 5 mg **Orexin receptor antagonist**	Suvorexant is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.	**Contraindications:** Suvorexant is contraindicated in patients with narcolepsy. **Side Effects:** The following serious adverse reactions are discussed in greater detail in other sections: CNS depressant effects and daytime impairment; abnormal thinking and behavioral changes; worsening of Depression/Suicidal ideation; Sleep paralysis, hypnagogic/hypnopompic hallucinations, cataplexy-like symptoms	New	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK i| †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK i| nj |
	Incepta Pharmaceuticals Limited	m)	Suvorexant 10 mg Tablet Suvorexant In house 10 mg **Orexin receptor antagonist**	Suvorexant is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.	**Contraindications:** Suvorexant is contraindicated in patients with narcolepsy. **Side Effects:** The following serious adverse reactions are discussed in greater detail in other sections: CNS depressant effects and daytime impairment; abnormal thinking and behavioral changes; worsening of Depression/Suicidal ideation; Sleep paralysis, hypnagogic/hypnopompic hallucinations, cataplexy-like symptoms	New	USFDA	Abyjgv`b K i| †h‡Z cv‡i |	Abyjgv`b K i| nj |
		n)	Suvorexant 15 mg Tablet Suvorexant In House 15mg **Orexin receptor antagonist**	Suvorexant is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.	Do	New	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK i| †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK i| nj |
		o)	Suvorexant 20 mg Tablet Suvorexant In House 20mg **Orexin receptor antagonist**	Suvorexant is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.	DO	New	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK i| †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK i| nj |
		p)	Racecadotril 10mg/Sachet Granules for oral suspension Racecadotril BP 10mg/Sachet **Antidiarrheals**	Complementary symptomatic treatment of acute diarrhea in infants (older than 3 months) and in children together with oral rehydration and the usual support measures, when these measures alone are insufficient to control the clinical condition, and when causal treatment is not possible. If causal treatment is possible, racecadotril can be administered as a complementary treatment	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients. This medicinal product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption syndrome or saccharase-isomaltase deficiency should not take this medicine. **Side Effects:** Infections and infestations: Uncommon: tonsillitis. Skin and subcutaneous tissue disorders: Uncommon: rash, erythema. Unknown: erythema multiforme, tongue edema, face edema, lip oedema, eyelid oedema, angioedema, urticaria, erythema nodosum, rash papular, prurigo, pruritus.	100mg Capsule	BNF no. 66 Page no. 6	Abyjgv`b K i| †h‡Z cv‡i |	Abyjgv`b K i| nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	q) Racecadotril 30mg/Sachet Granules for oral suspension Racecadotril BP 30mg/Sachet **Antidiarrheals**	Complementary symptomatic treatment of acute diarrhea in infants (older than 3 months) and in children together with oral rehydration and the usual support measures, when these measures alone are insufficient to control the clinical condition, and when causal treatment is not possible. If causal treatment is possible, racecadotril can be administered as a complementary treatment	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients. This medicinal product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption syndrome or saccharase-isomaltase deficiency should not take this medicine. **Side Effects:** Infections and infestations: Uncommon: tonsillitis. Skin and subcutaneous tissue disorders: Uncommon: rash, erythema. Unknown: erythema multiforme, tongue edema, face edema, lip oedema, eyelid oedema, angioedema, urticaria, erythema nodosum, rash papular, prurigo, pruritus.	100mg Capsule	BNF no. 66 Page no. 6	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		r) Rabeprazole Sodium 20mg + Diclofenac Sodium 100 mg sustained Release capsule Rabeprazole Sodium 15% Enteric Coated Pellets In House 133.3333mg eq. to 20mg Rabeprazole Sodium INN + Diclofenac Sodium 25% SR Pellets In House 400mg eq. to BP 100 mg Diclofenac Sodium INN **PPI + NSAIDS**	Dysmenorrhoea, Gastric ulcers, Gout, Hyperacidity, Low backache, Muscular relaxation during surgery, Orthopaedic manipulations & short surgeries, Osteo-arthritis, Peptic ulcer, Reflux oesophagitis, Rheumatic disorders, Rheumatoid arthritis, Sprains, Tracheal intubation	**Contraindications:** Angioneurotic edema, Cerebro-vascular accidents, Dehydration, First trimester of pregnancy, Hypersensitivity, Renal impairment, Urticaria **Side Effects:** Abdominal pain, Abnormal liver function tests, Angioneurotic edema, Anorexia, Arthralgia, Asthenia, Back pain, Bronchitis, Bronchospasm, Bullous eruptions, Chest pain, Constipation, Cough, Depression, Diarrhoea, Dizziness, Drowsiness, Dryness of mouth, Dyspepsia, Eosinophilia, Erythema, Eye irritation, Fever, Flatulence, Flu like symptoms, Fluid retention, G.I.Bleeding, G.I.Upset, Gastric irritation, Haematuria, Headache, Heart failure, Hepatotoxicity, Hypersensitivity, Increased sweating, Insomnia, Interstitial nephritis, Irritation and inflammation at the site of administration, Leucocytosis, Leukopenia, Local irritation, Local pain, Muscle cramps/pain, Nausea/vomiting, Nephritis, Nervousness, Neutropenia, Pancreatitis, Peptic ulcer, Pharyngitis, Photosensitization, Pruritis, Rash, Rhinitis, Sinusitis, Somnolence, Stevens-johnsons syndrome, Stomatitis, Taste disturbances, Thrombocytopenia, Tinnitus, Toxic epidermal necrolysis, Urinary tract infection, Vertigo, Visual disturbances, Weight gain.	Rabeprazole Sodium 10mg and 20mg Capsule		c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	s) Deflazacort 30mg Tablet Deflazacort In house 30mg **Glucocorticoid**	Oral Allergic and inflammatory disorder Hepatic impairment: Dose reductions may be needed.	**Contraindications:** Systemic infection; live virus vaccines in those receiving immunosuppressive doses. **Side Effects:** GI disturbances, musculoskeletal, endocrine, neuropsychiatric, ophthalmic, fluid and electrolyte disturbances; susceptible to infection, impaired healing, hypersensitivity, skin atrophy, striae, telangiectasia, acne, myocardial rupture following recent MI, thromboembolism.	6mg Tablet	BNF	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj |
		t) Deflazacort 6mg/5ml Oral suspension Deflazacort In House 6mg/5ml **Glucocorticoid**	Allergic and inflammatory disorder, Hepatic impairment: Dose reductions may be needed.	**Contraindications:** Systemic infection; live virus vaccines in those receiving immunosuppressive doses. **Side Effects:** GI disturbances, musculoskeletal, endocrine, neuropsychiatric, ophthalmic, fluid and electrolyte disturbances; susceptible to infection, impaired healing, hypersensitivity, skin atrophy, striae, telangiectasia, acne, myocardial rupture following recent MI, thromboembolism.	6mg Tablet		c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj |
		u) Racepinephrine 337.50mg/15ml Inhalation solution Racepinephrine HCl USP 405.00 mg eq. to 337.50mg Racepinephrine/15ml **Anti Asthmatic Agent**	For temporary relief of shortness of breath, tightness of chest, and wheezing due to bronchial asthma.	**Contraindications:** Within 14 days of MAOIs **Side Effects:** Nervousness, tachycardia with excessive use.	11.25mg/0.5ml Inhalation Solution		Abygv`b Kiv †h‡Z cv‡i |	Abygv`b Kiv nj |
		v) Aluminum Chloride Hexahydrate 15gm + Salicylic Acid 2gm/100gm Gel Aluminum Chloride Hexahydrate BP 15gm + Salicylic Acid BP 2gm/100gm	Directions : apply to underarms only	**Contraindications:** Do not use on broken, irritated or recently shaved skin. **Side Effects:** Burning	New		c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj |

bs	c¯ZKvi‡Ki bvg		Jl‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	x)	Finafloxacin 0.3gm/100ml Otic suspension Finafloxacin In House 0.3gm/100ml **Antibiotic**	finafloxacin otic suspension 0.3% is indicated for the treatment of acute otitis externa (AOE) with or without an otowick, caused by susceptible strains of Pseudomonas aeruginosa and Staphylococcus aureus in patients age 1 year and older.	**Contraindications:** None **Side Effects:** Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice. A total of 618 patients were treated with FINAFLOXACIN in two Phase 3 clinical trials. The most frequently reported adverse reactions of those exposed to FINAFLOXACIN occurring at an incidence of 1% included ear pruritus and nausea.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		y)	Hexamine 500mg + Piperazine Citrate 195mg + Khellin 1.83mg/Sachet Hexamine In House 500mg + Piperazine Citrate USP 195mg + Khellin In house 1.83mg/Sachet **Antibiotic + Antihelmenthic**	Chronic urinary tract infections, as in pyelitis, pyelonephritis, cystitis and infections accompanying neurogenic bladder. As a prophylaxis against urinary tract infection in patients with residual urine due to different causes including neuroloical ctseasss.os-proonqed bladder catheterization fast relif of urinary tract spasms and irritations caused by crystalluria and urinary calculi Prevention of urinary tract lithiasis	**Contraindications:** Hypersensitivity to any component of COMBINATION, severe hepatic diseases and renal insufficiency. **Side Effects:** COMBINATION is safe and well tolerated with almost no side effects However nausea, stomach upset Of rash might rarely occur.	New		c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyi Kiv nj
		z)	Praxomine Hydrochloride 1gm + Zinc Acetate 0.1gm + Camphor 0.05gm/100gm Lotion Praxomine Hydrochloride USP 1gm + Zinc Acetate USP 0.1gm + Camphor USP 0.05gm/100gm **Antipruritis & Local anesthetic**	Treating irritation and itching associated with skin conditions such as insect bites, minor cuts or irritation, or poison ivy, oak, or sumac. It may also be used for other conditions as determined by your doctor. This lotion is a protectant and anesthetic combination. It works by temporarily relieving itching and pain.	**Contraindications:** Known hypersensitivity to pramoxine or any ingredient in the formulation **Side Effects:** Local burning or stinging.	New		c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg		wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	aa)	Iron Sucrose 200mg/10ml Vial Injection Iron Sucrose USP 4gm eq. to Elemental Iron 200mg/10ml Vial **Iron suppliment**	Iron Sucrose is indicated for the treatment of iron deficiency anemia in patients with chronic kidney disease (CKD).	**Contraindications:** Known hypersensitivity to Iron Sucrose **Side Effects:** The most common adverse reactions (≥2%) following the administration of Venofer are diarrhea, nausea, vomiting, headache, dizziness, hypotension, and pruritus, pain in extremity, arthralgia, back pain, muscle cramp, injection site reactions, chest pain, and peripheral edema.	100 mg/5 ml Injection	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		ab)	Peramivir 200mg/20ml Vial IV Infusion Peramivir In House 200mg/20ml Vial **Antiviral**	PERAMIVIR is indicated for the treatment of acute uncomplicated influenza in patients 18 years and older who have been symptomatic for no more than 2 days. **Limitations of Use:** Efficacy of PERAMIVIR is based on clinical trials of naturally occurring influenza in which the predominant influenza infections were influenza A virus; a limited number of subjects infected with influenza B virus were enrolled. Influenza viruses change over time. Emergence of resistance substitutions could decrease drug effectiveness. Other factors (for example, changes in viral virulence) might also diminish clinical benefit of antiviral drugs. Prescribers should consider available information on influenza drug susceptibility patterns and treatment effects when deciding whether to use PERAMIVIR. The efficacy of PERAMIVIR could not be established in patients with serious influenza requiring hospitalization.	**Contraindications:** None **Side Effects:** The following adverse reactions are discussed in other sections of the labeling: • Serious skin and hypersensitivity reactions • Neuropsychiatric Events	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	ac) Ciclopirox Olamine 8gm/100ml Topical solution (Nail lacquer) Ciclopirox Olamine BP 8gm/100ml **Antifungal**	Ciclopirox Olamine Topical Solution, 8%, as a component of a comprehensive management program, is indicated as topical treatment in immunocompetent patients with mild to moderate onychomycosis of fingernails and toenails without lunula involvement, due to Trichophyton rubrum. The comprehensive management program includes removal of the unattached, infected nails as frequently as monthly, by a health care professional who has special competence in the diagnosis and treatment of nail disorders, including minor nail procedures. No studies have been conducted to determine whether ciclopirox might reduce the effectiveness of systemic antifungal agents for onychomycosis. Therefore, the concomitant use of 8% ciclopirox topical solution and systemic antifungal agents for onychomycosis, is not recommended. Ciclopirox olamine Topical Solution, 8%, should be used only under medical supervision as described above. The effectiveness and safety of Ciclopirox olamine Topical Solution, 8%, in the following populations has not been studied. The clinical trials with use of Ciclopirox olamine nail lacquer Topical Solution, 8%, excluded patients who: were pregnant or nursing, planned to become pregnant, had a history of immunosuppression (e.g., extensive, persistent, or unusual distribution of dermatomycoses, extensive seborrheic dermatitis, recent or recurring herpes zoster, or persistent herpes simplex), were HIV seropositive, received organ transplant, required medication to control epilepsy, were insulin dependent diabetics or had diabetic neuropathy. Patients with severe plantar (moccasin) tinea pedis were also excluded. The safety and efficacy of using Ciclopirox olamine Topical Solution, 8%, daily for greater than 48 weeks have not been established.	**Contraindications:** Ciclopirox Olamine Topical Solution, 8%, is contraindicated in individuals who have shown hypersensitivity to any of its components. **Side Effects:** The most common were rash-related adverse events: periungual erythema and erythema of the proximal nal fold were reported more frequently in patients treated with Ciclopirox Olamine Topical Solution, 8%, (5% [16/327]) than in patients treated with vehicle (1% [3/328]). Other TEAEs thought to be causally related included nail disorders such as shape change, irritation, ingrown toenail, and discoloration.	0.77% Cream and 1gm /100gm Shampoo	USFDA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	ad) Empagliflozin 10mg + Linagliptin 5mg tablet Empagliflozin In House 10mg + Linagliptin In House 5mg **Antidiabetic**	Empagliflozin + Linagliptin tablets are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both Empagliflozin and Linagliptin is appropriate. **Limitations of Use:** Empagliflozin + Linagliptin is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis. Empagliflozin + Linagliptin has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at an increased risk for the development of pancreatitis while using Empagliflozin + Linagliptin.	**Contraindications:** Empagliflozin + Linagliptin is contraindicated in patients with: Severe renal impairment, end-stage renal disease, or dialysis. A history of hypersensitivity reaction to linagliptin, such as anaphylaxis, angioedema, exfoliative skin conditions, urticaria, or bronchial hyperreactivity. History of serious hypersensitivity reaction to Empagliflozin. Side Effects: *Empagliflozin* Adverse reactions that occurred in ≥2% of patients receiving Empagliflozin and more commonly than in patients given placebo included (10 mg, 25 mg, and placebo): urinary tract infection (9.3%, 7.6%, and 7.6%), female genital mycotic infections (5.4%, 6.4%, and 1.5%), upper respiratory tract infection (3.1%, 4.0%, and 3.8%), increased urination (3.4%, 3.2%, and 1.0%), dyslipidemia (3.9%, 2.9%, and 3.4%), arthralgia (2.4%, 2.3%, and 2.2%), male genital mycotic infections (3.1%, 1.6%, and 0.4%), and nausea (2.3%, 1.1%, and 1.4%). Empagliflozin causes an osmotic diuresis, which may lead to intravascular volume contraction and adverse reactions related to volume depletion. *Linagliptin* Adverse reactions reported in ≥2% of patients treated with Linagliptin 5 mg and more commonly than in patients treated with placebo included: nasopharyngitis (7.0% and 6.1%), diarrhea (3.3% and 3.0%), and cough (2.1% and 1.4%). Other adverse reactions reported in clinical studies with treatment of Linagliptin monotherapy were hypersensitivity (e.g., urticaria, angioedema, localized skin exfoliation, or bronchial hyperreactivity) and myalgia.	Linagliptin 5mg tablet	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK iv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK iv nj |
		ae) Empagliflozin 25mg + Linagliptin 5mg Tablet Empagliflozin In house 25mg + Linagliptin In house 5mg **Antidiabetic**	Do	Do	Linagliptin 5mg tablet	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK iv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK iv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	af) Ferric Pyrophosphate Citrate 27.2 mg/5 ml Solution for IV Infusion Ferric Pyrophosphate Citrate In House 27.2 mg/5 ml **Iron suppliment**	Ferric Pyrophosphate Citrate is indicated for the replacement of iron to maintain hemoglobin in adult patients with hemodialysis-dependent chronic kidney disease (HDD-CKD). **Limitation Of Use:** Ferric Pyrophosphate Citrate is not intended for use in patients receiving peritoneal dialysis. Ferric Pyrophosphate Citrate has not been studied in patients receiving home hemodialysis.	**Contraindications:** None. **Side Effects:** The following adverse reactions are described below and elsewhere in the labeling: • Hypersensitivity Reactions	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		ag) Dapagliflozin 10mg Tablet Dapagliflozin Propanediol Monohydrate In-house 12.302mg eq. to 10mg Dapagliflozin **Antidiabetic**	Dapagliflozin is a sodium Glucose cotransporter-2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Limitation of Use:** Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	**Contraindications:** • History of a serious hypersensitivity reaction to Dapagliflozin • Severe renal impairment, End-stage renal disease (ESRD) or Patients on dialysis. **Side Effects:** The most common adverse reactions associated with it (5% or greater incidence) were female genital mycotic infections, Nasopharyngitis and urinary tract infections.	5mg Tablet	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK iv nj
		ah) Dalbavancin sterile powder 500mg/Vial Injection Dalbavancin HCl In-House 516mg eq. to 500mg Dalbavancin/Vial **Antibiotic**	Dalbvacin for injection is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: Staphylococcus aureus (including methicillin-susceptible and methicillin-resistant strains), Streptococcus pyogenes, Streptococcus agalactiae and Streptococcus anginosus group(including S. anginosus, S. intermedius, S. constellatus) **Usage**: To reduce the development of drug-resistant bacteria and maintain the effectiveness of Dalbvacin and other antibacterial agents, Dalbvacin should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.	**Contraindications:** Dalbvacin is contraindicated in patients with known hypersensitivity to dalbavancin. **Side Effects:** The most common adverse reactions in patients treated with Dalbavancin were nausea (5.5%), headache (4.7%), and diarrhea (4.4%).	New	USFDA	Abyjgv`b Kiv ‡h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	Jl‡ai bvg I †RvbwiK bvg		wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	ai)	Dulaglutide 0.75mg/0.5ml Prefilled Syringe for Injection Dulaglutide In-House 0.75mg/0.5ml **Antidiabetic**	Dulaglutide is a glucagon –like peptide (GLP-1) receptor agnist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Limitations of Use:** • Dulaglutide is not recommended as a first-line therapy for patients who have inadequate glycemic control on diet and exercise. • Dulaglutide has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis. • Dulaglutide should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Dulaglutide is not a substitute for insulin. • Dulaglutide has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis. • The use of Dulaglutide is not recommended in patients with pre-existing severe gastrointestinal disease • The concurrent use of Dulaglutide and basal insulin has not been studied.	**Contraindications:** Medullary Thyroid Carcinoma Dulaglutide is contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2. Hypersensitivity: Dulaglutide is contraindicated in patients with a prior serious hypersensitivity reaction to dulaglutide or to any of the product components. **Side Effects:** The following serious reactions are described below or elsewhere in the labeling: • Risk of Thyroid C-cell Tumors • Pancreatitis • Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin • Hypersensitivity reactions • Renal impairment	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		ak)	Dulaglutide 1.5mg/0.5ml Injection Dulaglutide In house 1.5mg/0.5ml **Antidiabetic**	Do	Do	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	al) Oritavancin Lyophilized Powder 400mg/Vial Injection Oritavancin Diphosphate In-House 443.457mg eq. to 400mg Oritavancin/Vial **Antibiotic**	Acute Bacterial Skin and Skin Structure Infections Oritavancin for injection is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: *Staphylococcus aureus* (including methicillin-susceptible and methicillin–resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Streptococcus dysgalactiae*, *Streptococcus anginosus* group (includes *S. anginosus*, *S. intermedius*, and *S. constellatus*), and *Enterococcus faecalis* (vancomycin-susceptible isolates only). **Usage**: To reduce the development of drug-resistant bacteria and maintain the effectiveness of Oritavancin and other antibacterial drugs, Oritavancin should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.	**Contraindications:** Intravenous Unfractionated Heparin Sodium Use of intravenous unfractionated heparin sodium is contraindicated for 48 hours after Oritavancin administration because the activated partial thromboplastin time (aPTT) test results are expected to remain falsely elevated for approximately 48 hours after Oritavancin administration *Hypersensitivity:* Oritavancin is contraindicated in patients with known hypersensitivity to Oritavancin. **Side Effects:** The following adverse reactions are also discussed in the Warnings and Precautions section of the label: ♦ Hypersensitivity Reactions ♦ Infusion related reactions ♦ *Clostridium difficile*-associated diarrhea	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvMvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	am) Ledipasvir 90mg + Sofosbuvir 400mg Tablet Ledipasvir In-House 90mg + Sofosbuvir In-House 400mg **Antiviral**	Ledipasvir & Sofosbuvir Tablet is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults.	**Contraindications:** None known. **Side Effects:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The safety assessment of Ledipasvir & Sofosbuvir was based on pooled data from three Phase 3 clinical trials of subjects with genotype 1 chronic hepatitis C (CHC) with compensated liver disease (with and without cirrhosis) including 215, 539, and 326 subjects who received Ledipasvir & Sofosbuvir for 8, 12 and 24 weeks, respectively The proportion of subjects who permanently discontinued treatment due to adverse events was 0%, <1%, and 1% for subjects receiving Ledipasvir & Sofosbuvir for 8, 12, and 24 weeks, respectively. The most common adverse reactions (≥10%) were fatigue and headache in subjects treated with 8, 12, or 24 weeks of Ledipasvir & Sofosbuvir. <u>Laboratory Abnormalities</u> *Bilirubin Elevations:* Bilirubin elevations of greater than 1.5xULN were observed in 3%, <1% and 2% of subjects treated with ledipasvir & sofosbuvir for 8, 12, and 24 weeks, respectively. *Lipase Elevations:* Transient, asymptomatic lipase elevations of greater than 3xULN were observed in <1%, 2%, and 3% of subjects treated with Ledipasvir & Sofosbuvir for 8, 12, and 24 weeks, respectively. *Creatine Kinase:* Creatine kinase was not assessed in Phase 3 trials Ledipasvir & Sofosbuvir. Isolated, asymptomatic creatine kinase elevations (Grade 3 or 4) have been previously reported in subjects treated with sofosbuvir in combination with ribavirin or peginterferon/ribavirin in other clinical trials.	Sofosbuvir 400mg Tablet	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	Jl‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	an) Lisdexamfetamine Dimesylate 20mg Capsule Lisdexamfetamine Dimesylate In-House 20mg **CNS Stimulant**	Lisdexamfetamine dimesylate is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).	**Contraindications:** Lisdexamfetamine is contraindicated in patients with: - Known hypersensitivity to amphetamine products or other ingredients of Lisdexamfetamine. Anaphylactic reactions, Stevens - Johnson syndrome, angioedema, and urticaria have been observed in postmarketing reports. - Concurrent administration of monoamine oxidase inhibitors (MAOI) or administration of Lisdexamfetamine within 14 days of the last MAOI dose. Hypertensive crisis can occur. **Side Effects:** The following adverse reactions are discussed in greater detail in other sections of the labeling - Serious Cardiovascular Reactions - Blood Pressure and Heart Rate Increases - Psychiatric Adverse Reactions - Suppression of Growth - Peripheral Vasculopathy, including Raynaud's phenomenon	New	USFDA	ïaygvÎv Attention Deficit Hyperactivity Disorder (ADHD) wb‡`kbvq e¨envi n‡e, GB k‡Z Abyôgv`b Kiv †h‡Z cv‡i	ïaygvÎv Attention Deficit Hyperactivity Disorder (ADHD) wb‡`kbvq e¨envi n‡e, GB k‡Z Abyôgv`b Kiv nj|
		ao) Apremilast 10mg Tablet Apremilast In-House 10mg **Antiinflammatory**	Apremilast is indicated for the treatment of adult patients with active psoriatic arthritis	**Contraindications:** Apremilast is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation **Side Effects:** Adverse reactions reported in patients on Apremilast in clinical studies including extension studies: Immune system disorders: Hypersensitivity Investigations: Weight decrease Gastrointestinal Disorders: Frequent bowel movement, gastroesophageal reflux disease, dyspepsia Metabolism and Nutrition Disorders: Decreased appetite Nervous System Disorders: Migraine Respiratory, Thoracic, and Mediastinal Disorders: Cough Skin and Subcutaneous Tissue Disorders: Rash	New	USFDA	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj|

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	ap) Apremilast 20mg Tablet Apremilast In-house 20mg **Antiinflammatory**	Apremilast is indicated for the treatment of adult patients with active psoriatic arthritis	**Contraindications:** Apremilast is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation **Side Effects:** Adverse reactions reported in patients on Apremilast in clinical studies including extension studies: Immune system disorders: Hypersensitivity Investigations: Weight decrease Gastrointestinal Disorders: Frequent bowel movement, gastroesophageal reflux disease, dyspepsia Metabolism and Nutrition Disorders: Decreased appetite Nervous System Disorders: Migraine Respiratory, Thoracic, and Mediastinal Disorders: Cough Skin and Subcutaneous Tissue Disorders: Rash	New	USFDA	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj
		aq) Apremilast 30mg Tablet Apremilast In-house 30mg **Antiinflammatory**	Do	Do	New	USFDA	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj
		ar) Palonosetron 0.5mg + Netupitant 300mg Capsule Palonosetron In-House 0.5mg + Netupitant In-House 300mg **Antiemetic Combination**	Palonosetron with Netupitant is indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Palonosetron + Netupitant are an oral fixed combination of palonosetron and netupitant: palonosetron prevents nausea and vomiting during the acute phase and netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.	**Contraindications:** None known. **Side Effects:** The following adverse reactions are Dyspepsia, Fatigue, Constipation, Erythema, Headache, Asthenia	Palonosetron 0.5mg Tablet	USFDA	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	as) Lurasidone HCl 20mg Tablet Lurasidone HCl In-House 20mg **Antipsychotic agent**	Lurasidone HCl is indicated for the treatment of patients with schizophrenia. The efficacy of Lurasidone HCl in schizophrenia was established in four 6-week controlled studies of adult patients with schizophrenia. The effectiveness of Lurasidone HCl for longer-term use, that is, for more than 6 weeks, has not been established in controlled studies. Therefore, the physician who elects to use Lurasidone HCl for extended periods should periodically re-evalu ate the long-term usefulness of the drug for the individual patient	Contraindications: Lurasidone HCl is contraindicated in any patient with a known hypersensitivity to lurasidone HCl or any components in the formulation. Angioedema has been observed with lurasidone. Lurasidone HCl is contraindicated with strong CYP3A4 inhibitors (e.g., ketoconazole) and strong CYP3A4 inducers (e.g., rifampin) Side Effects: The following adverse reactions are discussed in more detail in other sections of the labeling: Use in Elderly Patients w ith Dementia-Related Psychosis, Cerebrovascular Adverse Reactions, Including Stroke, Neuroleptic Malignant Syndrome, Tardive Dyskinesia, Hyperglycemia and Diabetes Mellitus, Hyperprolactinemia, Leukopenia, Neutropenia, and Agranulocytosis, Orthostatic Hypotension and Syncope, Seizures, Potential for Cognitive and Motor Impairment, Body Temperature Regulation, Suicide, Dysphagia, Use in Patients with Concomitant Illness.	40mg Tablet	USFDA	Abyôv`b Kiv †h‡Z cv‡i	Abyôv`b Kiv nj
		at) Albiglutide 30mg/Vial lyophilized powder for reconstitution for Injection Albiglutide In House 30mg/Vial **Antidiabetic**	ALBIGLUTIDE is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Limitatiozns of Use** ALBIGLUTIDE is not recommended as first-line therapy for patients inadequately controlled on diet and exercise. It has not been studied in patients with a history of pancreatitis. It is not indicated in the treatment of patients with type 1 diabetes mellitus or for the treatment of patients with diabetic ketoacidosis. It is not a substitute for insulin in these patients. It has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis. The use of ALBIGLUTIDE is not recommended in patients with pre-existing severe gastrointestinal disease. It has not been studied in combination with prandial insulin.	**Contraindications:** Medullary Thyroid Carcinoma ALBIGLUTIDE is contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Hypersensitivity ALBIGLUTIDE is contraindicated in patients with a prior serious hypersensitivity reaction to albiglutide or to any of the product components. **Side Effects:** The following serious reactions are described below or elsewhere in the labeling: • Risk of Thyroid C-cell Tumors • Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin • Hypersensitivity Reactions • Renal Impairment	New	USFDA	Abyôv`b Kiv †h‡Z cv‡i	Abyôv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	au) Albiglutide 50mg/Vial lyophilized powder for reconstitution for Injection Albiglutide In House 50mg/Vial **Antidiabetic**	ALBIGLUTIDE is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Limitatiozns of Use** ALBIGLUTIDE is not recommended as first-line therapy for patients inadequately controlled on diet and exercise. It has not been studied in patients with a history of pancreatitis. It is not indicated in the treatment of patients with type 1 diabetes mellitus or for the treatment of patients with diabetic ketoacidosis. It is not a substitute for insulin in these patients. It has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis. The use of ALBIGLUTIDE is not recommended in patients with pre-existing severe gastrointestinal disease. It has not been studied in combination with prandial insulin.	**Contraindications:** Medullary Thyroid Carcinoma ALBIGLUTIDE is contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Hypersensitivity ALBIGLUTIDE is contraindicated in patients with a prior serious hypersensitivity reaction to albiglutide or to any of the product components. **Side Effects:** The following serious reactions are described below or elsewhere in the labeling: • Risk of Thyroid C-cell Tumors • Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin • Hypersensitivity Reactions • Renal Impairment	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
		av) Fludrocortisone Acetate 0.100mg Tablet Fludrocortisone Acetate BP 0.100 mg **Steroid**	Fludrocortisone Acetate is indicated as partial replacement therapy for primary and secondary adrenocortical insufficiency in Addison's disease and for the treatment of salt-losing adrenogenital syndrome.	**Contraindications:** Corticosteroids are contraindicated in patients with systemic fungal infections and in those with a history of possible or known hypersensitivity to these agents. **Side Effects:** Most adverse reactions are caused by the drug's mineralocorticoid activity (retention of sodium and water) and include hypertension, edema, cardiac enlargement, congestive heart failure, potassium loss, and hypokalemic alkalosis. When fludrocortisone is used in the small dosages recommended, the glucocorticoid side effects often seen with cortisone and its derivatives are not usually a problem; however the following untoward effects should be kept in mind, particularly when fludrocortisone is used over a prolonged period of time or in conjunction with cortisone or a similar glucocorticoid. Musculoskeletal-muscle weakness, steroid myopathy, loss of muscle mass, osteoporosis, vertebral compression fractures, aseptic necrosis of femoral and humeral heads, pathologic fracture of long bones, and spontaneous fractures. Gastrointestinal-peptic ulcer with possible perforation and hemorrhage, pancreatitis, abdominal distention, and ulcerative esophagitis. Dermatologic-impaired wound healing, thin fragile skin, bruising, petechiae and ecchymoses, facial erythema, increased sweating, subcutaneous fat atrophy, purpura, striae, hyperpigmentation of the skin and nails, hirsutism, acneiform eruptions, and hives; reactions to skin tests may be suppressed. Neurological-convulsions, increased intracranial pressure with papilledema (pseudotumor erebri) usually after treatment, vertigo, headache, and severe mental disturbances. Endocrine-menstrual irregularities; development of the cushingoid state; suppression of growth in children; secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress (e.g., trauma, surgery, or illness); decreased carbohydrate tolerance; manifestations of latent diabetes mellitus; and increased requirements for insulin or oral hypoglycemic agents in diabetics. Ophthalmic-posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and exophthalmos. Metabolic-hyperglycemia, glycosuria, and	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

				negative nitrogen balance due to protein catabolism. Allergic Reactions-allergic skin rash, maculopapular rash, and urticaria. Other adverse reactions that may occur following the administration of a corticosteroid are necrotizing angiitis, thrombophlebitis, aggravation or masking of infections, insomnia, syncopal episodes, and anaphylactoid reactions.				
	Incepta Pharmaceuticals Limited	aw) Calcium Polystyrene Sulfonate 300gm/Container Suspension Calcium Polystyrene Sulfonate BP 300gm/Container **Potassium Removing Agent**	Calcium polystyrene sulfonate is indicated in patients with hyperkalemia associated with anuria or severe oliguria. It reduces serum levels of potassium and removes excess potassium from the body. Calcium polystyrene sulfonate is indicated in all states of hyperkalemia due to acute and chronic renal failure; examples include use following abortion, complicated labor, incompatible blood transfusion, crush injury, prostatectomy, severe burns, surgical shock, and in cases of severe glomerulonephritis and pyelonephritis. Calcium polystyrene sulfonate can also be useful in patients requiring dialysis. Serum potassium levels in acute renal failure often reach dangerous heights before a rise in blood urea indicates the need for hemodialysis. Calcium polystyrene sulfonate can be used to reduce these potassium levels and thereby postpone the need for the use of the artificial kidney machine until other causes make it necessary. Patients on regular hemodialysis therapy may develop shunt difficulties and underdialysis occurs, resulting in serious hyperkalemia. In these circumstances it is advisable to give the resin to control hyperkalemia during the period of underdialysis. Monitoring serum potassium and calcium levels should be undertaken at regular intervals. When patients on routine hemodialysis present a dietary management problem and tend	**Contraindications:** Calcium polystyrene sulfonate should not be administered to patients with: • Serum potassium < 5 mmol/L • Conditions associated with hypercalcemia (e.g. hyperparathyroidism, multiple myeloma, sarcoidosis or metastic carcinoma) • A history of hypersensitivity to polystyrene sulfonate resins • Obstructive bowel disease Oral administration of Calcium polystyrene sulfonate is contraindicated in neonates. Administration of the resin in neonates with reduced gut motility (postoperatively or drug induced) is contraindicated. **Side Effects:** Gastrointestinal disorders: Intestinal intolerance due to the gritty consistency and bulk of the resin may be manifested by the appearance of general adverse effects including nausea, vomiting, gastric irritation, anorexia, constipation and occasionally, diarrhea. These adverse effects may be relieved by intermittent therapy and the use of mild laxatives where constipation is a factor. Fecal impactions following rectal administration, particularly in children, and gastrointestinal concretions (bezoars) following oral administration, have been reported. Gastrointestinal stenosis and intestinal obstruction have also been reported. This could possibly due to co-existing pathology or inadequate dilution of the resin. Gastrointestinal ischemia, ischemic colitis, rectal haemorrhage, gastrointestinal tract ulceration or necrosis which could lead to intestinal perforation have been reported which is sometimes fatal. The majority of cases have been reported with concomitant use of sorbitol.	New	BNF 67 Page:651	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

			towards hyperkalemia, Calcium polystyrene sulfonate can be used to control blood potassium levels. Similarly, patients on prolonged peritoneal dialysis may develop intermittent hyperkalemia after a few weeks, possibly due to dietary problems. These patients also can be satisfactorily controlled with Calcium polystyrene sulfonate.	Metabolism and nutrition disorders: In accordance with its pharmacological actions, Calcium polystyrene sulfonate may give rise to hypokalemia and hypercalcemia and their related clinical manifestations. Cases of hypomagnesemia have been reported. Hypercalcemia has been reported in well dialysed patients receiving calcium resin, and occasionally in patients with chronic renal failure. Respiratory, thoracic and mediastinal disorders: Some cases of acute bronchitis and/or bronchopneumonia associated with inhalation of particles of calcium polystyrene sulfonate have been described.				
	Incepta Pharmaceuticals Limited	ax) Oxycodone Hydrochloride 10mg Extended Release Tablet Oxycodone HCl USP10mg **Narcotic Analgesic**	Oxycodone Hydrochloride is indicated for the management of pain severe enough to require daily, aroundthe-clock, long-term opioid treatment and for which alternative treatment options are inadequate. **Limitations of Use** Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve Oxycodone Hydrochloride for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. Oxycodone Hydrochloride is not indicated as an as-needed (prn) analgesic	**Contraindications:** Oxycodone Hydrochloride is contraindicated in patients with: • Significant respiratory depression • Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment • Known or suspected paralytic ileus and gastrointestinal obstruction • Hypersensitivity (e.g., anaphylaxis) to oxycodone Side Effects: The following serious adverse reactions are seen: • Addiction, Abuse, and Misuse • Life-Threatening Respiratory depression • Neonatal Opioid Withdrawal Syndrome • Interactions with Other CNS Depressants • Hypotensive Effects	New	USFDA BNF 67; Page: 283	*c‡qvRb †bB wea vq Avi‡e`b bvgÄyÿ K i v †h‡Z cv‡i |*	*c‡qvRb ‡bB wea vq Avi‡e`b bvgÄyÿ K i v n j |*

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	ay) Oxycodone Hydrochloride Extended Release 15mg Tablet Oxycodone HCl USP 15mg **Narcotic Analgesic**	Do	Do	New	USFDA BNF 67 Page: 283	c‡qvRb †bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj
		az) Oxycodone Hydrochloride Extended Release 20mg tablet Oxycodone HCl USP 20mg **Narcotic Analgesic**	Do	Do	New	USFDA BNF 67 Page: 283	c‡qvRb †bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj
		aaa) Canagliflozin 50mg + Metformin HCl 500mg Tablet Canagliflozin Hemihydrate In House 51.00mg eq. to 50mg Canagliflozin + Metformin Hydrochloride BP/USP 500 mg **Antidiabetic**	This combination is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing metformin or canagliflozin, or in patients who are already treated with both canagliflozin and metformin Limitations of Use It is not recommended in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.	Contraindications: This combination is contraindicated in patients with: • Renal impairment (e.g., serum creatinine levels greater than or equal to 1.5 mg/dL for males or 1.4 mg/dL for females, or eGFR is less than 45 mL/min/1.73 m2) which may also result from conditions such as cardiovascular collapse (shock), acute myocardial infarction, and septicemia; end stage renal disease (ESRD) or patients on dialysis. • Acute or chronic metabolic acidosis, including diabetic ketoacidosis. • History of a serious hypersensitivity reaction to canagliflozin or metformin. Side Effects: The following adverse reactions are also discussed elsewhere in the labeling: • Lactic Acidosis • Hypotension • Impairment in Renal Function • Hyperkalemia • Impaired Hepatic Function • Hypoglycemia with Concomitant Use of Sulfonylurea or Insulin • Genital Mycotic Infections • Hypersensitivity Reactions • Vitamin B12 Deficiency • Increases in Low-Density Lipoprotein (LDL-C)	New	USFDA	c‡qvRb †bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	aab) Canagliflozin 150mg + Metformin HCl 500mg Tablet Canagliflozin Hemihydrate In House 153.00mg eq. to 150mg Canagliflozin + Metformin Hydrochloride BP/USP500 mg **Antidiabetic**	Do	Do	New	USFDA	c‡qvRb †bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj	
		aac) Canagliflozin 50mg + Metformin HCl 1000mg Tablet Canagliflozin Hemihydrate In House 51.00mg eq. to 50mg Canagliflozin + Metformin Hydrochloride BP/USP1000 mg **Antidiabetic**	Do	Do	New	USFDA	c‡qvRb †bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj	
		aad) Canagliflozin 150mg + Metformin HCl 1000mg Tablet Canagliflozin Hemihydrate In House 153.00mg eq. to 150mg Canagliflozin + Metformin Hydrochloride BP/USP1000 mg **Antidiabetic**	Do	Do	New	USFDA	c‡qvRb †bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj	

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	aae) Calamine 8gm + Pramoxine HCl 1.0gm/100gm Cream Calamine BP 8gm + Pramoxine HCl USP 1.0gm/100gm **Topical Anaesthetic**	Topical Pain, For the relief of itching, pain, and discomfort of ivy, oak, sumac poisoning	**Contraindications:** Hypersensitivity to any product component **Side Effects:** Irritation, Pruritus	New		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		aaf) Prednisolone 50mg Tablet Prednisolone BP 50mg **Glucocorticosteroid**	Prednisolone tablets are indicated in the following conditions: *Endocrine Disorders:* Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the first choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy mineralocorticoid supplementation is of particular importance). Congenital adrenal hyperplasia. Hypercalcemia associated with cancer. Nonsuppurative thyroiditis. *Rheumatic Disorders:* As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis. Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy). Ankylosing spondylitis. Acute and subacute bursitis. Acute nonspecific tenosynovitis. Acute gouty arthritis. Post-traumatic osteoarthritis. Synovitis of osteoarthritis. Epicondylitis. *Collagen Diseases:* During an exacerbation or as maintenance therapy in selected cases of: Systemic lupus erythematosus. Systemic dermatomyositis (polymyositis). Acute rheumatic carditis. *Dermatological Diseases:*	**Contraindications:** Systemic fungal infections and known hypersensitivity to components. **Side Effects:** Fluid and Electrolyte Disturbances: Sodium retention, fluid retention, congestive heart failure in susceptible patients, potassium loss, hypokalemic alkalosis, and hypertension. *Musculoskeletal*: Muscle weakness, steriod myopathy, loss of muscle mass, osteoporosis, tendon rupture, particularly of the Achilles tendon, vertebral compression fractures, aseptic necrosis of femoral and humeral heads, and pathologic fracture of long bones. *Gastrointestinal*: Peptic ulcer with possible perforation and hemorrhage; pancreatitis; abdominal distention; ulcerative esophagitis; Increases in alanine transaminase (ALT, SGPT), aspartate transaminase (AST, SGOT) and alkaline phosphatase have been observed following corticosteroid treatment. These changes are usually small, not associated with any clinical syndrome and are reversible upon discontinuation. *Dermatologic*: Impaired wound healing, thin fragile skin, petechiae and ecchymoses, facial erythema, increased sweating, and may suppress reactions to skin tests. *Metabolic:* Negative nitrogen balance due to protein catabolism. *Neurological:* Increased intracranial pressure with papilledema (pseudo-tumor cerebri) usually after treatment, convulsions, vertigo, and headache.	2mg/5mg/10mg/ 20mg Tablet	USFDA	GB gvÎv c‡qvRb †bB wewfbœ Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	GB gvÎv c‡qvRb ‡bB wewfbœ Av‡e`b bvgÄyi Kiv nj

			Pemphigus. Bullous dermatitis herpetiformis. Severe erythema muliforme (Stevens-Johnson syndrome). Exfoliative dermatitis. Mycosis fungoides. Severe psoriasis. Severe seborrheic dermatitis. *Allergic States:* Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment: Seasonal or perennial allergic rhinitis. Bronchial asthma. Contact dermatitis. Atopic dermatitis. Serum sickness. Drug hypersensitivity reactions. *Ophthalmic Diseases:* Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: Allergic corneal marginal ulcers. Herpes zoster ophthalmicus. Anterior segment inflammation. Diffuse posterior uveitis and choroiditis. Sympathetic ophthalmia. Allergic conjunctivitis. Keratitis. Chorioretinitis. Optic neuritis. Iritis and iridocyclitis. *Respiratory Diseases:* Symptomatic sarcoidosis. Loeffler's syndrome not manageable by other means. Berylliosis. Fulminating or disseminated pulmonary tuberculosis when used concurrently with appropriate antituberculous chemotherapy. Aspiration pneumonitis. *Hematologic Disorders:* Idiopathic thrombocytopenic purpura in adults. Secondary thrombocytopenia in adults. Acquired (autoimmune) hemolytic anemia. Erythroblastopenia (RBC anemia). Congenital (erythroid) hypoplastic anemia. *Neoplastic Diseases*: For palliative management of: Leukemias and lymphomas in adults. Acute leukemia of childhood. *Edematous States:* To induce a diuresis or remission of	Endocrine: Menstrual irregularities; development of Cushingoid state; secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness; suppression of growth of children; decreased carbohydrate tolerance; manifestations of latent diabetes mellitus; increased requirements for insulin or oral hypoglycemic agents in diabetics. *Ophthalmic:* Posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and exophthalmos. *Additional Reactions:* Urticaria and other allergic, anaphylactic or hypersensitivity reactions.				

			proteinuria in the nephrotic syndrome, without uremia, of the idiopathic type or that due to lupus erythematosus. *Gastrointestinal Diseases*: To tide the patient over a critical period of the disease in: Ulcerative colitis. Regional enteritis. *Nervous System:* Acute exacerbations of multiple sclerosis. *Miscellaneous:* Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy. Trichinosis with neurologic or myocardial involvement.					
	Incepta Pharmaceuticals Limited	aag) Calcium Orotate 1100mg+ Magnesium Orotate 550mg + Opti MSM 80mg Capsule Calcium Orotate dihydrate In House 1213.047mg eq. to eq. to calcium Orotate 1100mg+ Magnesium Orotate In House 550mg + Opti Methylsulfonylmethane In House 80mg **Minerals**	This Capsule is used – 1. To prevent or treat low blood calcium levels in people who do not get enough calcium from diets. 2. To fulfill the calcium deficiency or meet extra need of calcium in conditions like- Osteomalacia, Rickets, Latent tetany, Postmenopausal osteoporosis, Senile osteoporosis, Juvenile osteoporosis, Drug induced osteoporosis(Phenytoin, Phenobarbital, or Prednisone), Pregnancy and lactation, Premenstrual syndrome (PMS), Hypoparathyroidism, Hip joint plastic surgery 3. Acts against a number of inflammatory diseases like - Arthritis, Multiple sclerosis, Spondylitis 4. Helps in controlling weight by suppressing the habit of frequentappetite of chronic overeaters. 5. It is also beneficial in reducing the effects of mood swings. 6. Proved to be quite effective in cognitive enhancement. 7. Protects the heart by enhancing the efficiency of cardiac muscles	**Contraindications:** Calcium orotate is contraindicated in conditions like kidney stone, kidney disease, increased activity of the parathyroid gland, high amount of calcium in urine, high amount of calcium in the blood, extreme loss of body water. **Side Effects:** Bloating and swelling in the abdomen are common side effects of Calcium Orotate. Constipation, nausea, vomiting, headache, increased thirst/urination, may occur infrequently.	Calcium Orotate 400mg and 740mg Tablet		*c‡qvRb †bB wea vq Av‡e`b bvgÄy Kiv †h‡Z cv‡i |*	*c‡qvRb †bB wea vq Av‡e`b bvgÄy Kiv nj |*

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Ltd.	aah) Tositumomab 225mg/Vial Injection Tositumomab In-House 225mg/Vial **Anticancer (Antineoplastic Agent)**	<u>Relapsed or Refractory CD20-Positive, Non-Hodgkin's Lymphoma</u> The Tositumomab therapeutic regimen (tositumomab and iodine I 131 tositumomab) is indicated for the treatment of patients with CD20-positive relapsed or refractory, low grade, follicular, or transformed non-Hodgkin's lymphoma who have progressed during or after rituximab therapy, including patients with rituximab-refractory non-Hodgkin's lymphoma. Determination of the effectiveness of the Tositumomab therapeutic regimen is based on overall response rates in patients whose disease is refractory to chemotherapy and rituximab. The effects of the Tositumomab therapeutic regimen on survival are not known. **<u>Important Limitations of Use</u>** • The Tositumomab therapeutic regimen is only indicated for a single course of treatment. • The safety and efficacy of additional courses of the Tositumomab therapeutic regimen have not been established. • The Tositumomab therapeutic regimen is not indicated for first-line treatment of patients with CD20-positive non-Hodgkin's lymphoma.	**Contraindications:** None **Side Effects**: The following serious adverse reactions are discussed in greater detail in other sections of the label: • Serious Allergic Reactions, Including Anaphylaxis • Prolonged and Severe Cytopenias • Secondary malignancies • Hypothyroidism	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	aai) Ustekinumab 90mg/ml Injection Ustekinumab In-House 90mg/ml **Immunological Agent/Cytokine modulator**	Psoriasis (Ps) Ustekinumab is indicated for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. Psoriatic Arthritis (PsA) Ustekinumab is indicated for the treatment of adult patients (18 years or older) with active psoriatic arthritis. Ustekinumab can be used alone or in combination with methotrexate(MTX).	**Contraindications:** Clinically significant hypersensitivity to ustekinumab or to any of the excipients. **Side Effects:** The following serious adverse reactions are discussed elsewhere in the label: Infections, Malignancies, Reversible Posterior Leukoencephalopathy Syndrome	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj	
		aaj) Ustekinumab 45mg/0.5ml Injection Ustekinumab In-house 45mg/0.5ml **Immunological Agent/Cytokine modulator**	Psoriasis (Ps): Ustekinumab is indicated for the treatment of adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. Psoriatic Arthritis (PsA) Ustekinumab is indicated for the treatment of adult patients (18 years or older) with active psoriatic arthritis. Ustekinumab can be used alone or in combination with methotrexate (MTX).	**Contraindications:** Clinically significant hypersensitivity to ustekinumab or to any of the excipients. Side Effects: The following serious adverse reactions are discussed elsewhere in the label: • Infections • Malignancies • Reversible Posterior Leukoencephalopathy Syndrome	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj	
		aak) Palivizumab 100mg/ml Vial Injection Palivizumab In-House 100mg/ml Vial **Antiviral Monoclonal Antibody**	Palivizumab is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease. The following points should be considered when prescribing Palivizumab: 1. Safety and efficacy were established in children with bronchopulmonary dysplasia (BPD), infants with a history of premature birth (less than or equal to 35 weeks gestational age), and children with hemodynamically significant congenital heart disease (CHD). 2. The safety and efficacy of Palivizumab have not been established for treatment of RSV disease.	**Contraindications:** Palivizumab is contraindicated in children who have had a previous significant hypersensitivity reaction to Palivizumab. **Side Effects:** The most serious adverse reactions occurring with Palivizumab are anaphylaxis and other acute hypersensitivity reactions	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj	

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbvwiK bvg		wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	aal)	Palivizumab 50mg/0.5ml Vial Injection Palivizumab In-house 50mg/0.5ml Vial **Antiviral Monoclonal Antibody**	Palivizumab is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease. The following points should be considered when prescribing Palivizumab: 1. Safety and efficacy were established in children with bronchopulmonary dysplasia (BPD), infants with a history of premature birth (less than or equal to 35 weeks gestational age), and children with hemodynamically significant congenital heart disease (CHD). 2. The safety and efficacy of Palivizumab have not been established for treatment of RSV disease.	**Contraindications:** Palivizumab is contraindicated in children who have had a previous significant hypersensitivity reaction to Palivizumab. **Side Effects:** The most serious adverse reactions occurring with Palivizumab are anaphylaxis and other acute hypersensitivity reactions	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		aam)	Alemtuzumab 12mg/1.2ml Vial Injection Alemtuzumab In-house 12mg/1.2ml Vial **Immunological Agent**	Alemtuzumab is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS). Because of its safety profile, the use of Alemtuzumab should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of multiple sclerosis	**Contraindications:** Alemtuzumab is contraindicated in patients who are infected with Human Immunodeficiency Virus (HIV) because Alemtuzumab causes prolonged reductions of CD4+ lymphocyte counts. **Side Effects:** The following serious adverse reactions are described below and elsewhere in the labeling: Autoimmunity, Infusion reactions Malignancies, Immune Thrombocytopenia, Glomerular Nephropathies, Thyroid Disorder, Other Autoimmune Cytopenias, Infections and Pneumonitis	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	aan) Ranibizumab 10mg/ml Vial Injection Ranibizumab In-House 10mg/ml Vial **Opthalmological Agent**	RANIBIZUMAB is indicated for the treatment of patients with: • Neovascular (Wet) Age-Related Macular Degeneration (AMD) • Macular Edema Following Retinal Vein Occlusion (RVO) • Diabetic Macular Edema (DME)	**Contraindications:** Ocular Or Periocular Infections RANIBIZUMAB is contraindicated in patients with ocular or periocular infections. Hypersensitivity RANIBIZUMAB is contraindicated in patients with known hypersensitivity to ranibizumab or any of the excipients in RANIBIZUMAB. Hypersensitivity reactions may manifest as severe intraocular inflammation. **Side Effects:** The following adverse reactions are discussed • Endophthalmitis and Retinal Detachments • Increases in Intraocular Pressure • Thromboembolic Events • Fatal Events in DME Patients	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		aao) Ranibizumab 6mg/ml Vial Injection Ranibizumab In-house 6mg/ml **Opthalmological Agent**	RANIBIZUMAB is indicated for the treatment of patients with: - Neovascular (Wet) Age-Related Macular Degeneration (AMD) - Macular Edema Following Retinal Vein Occlusion (RVO) - Diabetic Macular Edema (DME)	**Contraindications:** Ocular Or Periocular Infections RANIBIZUMAB is contraindicated in patients with ocular or periocular infections. Hypersensitivity RANIBIZUMAB is contraindicated in patients with known hypersensitivity to ranibizumab or any of the excipients in RANIBIZUMAB. Hypersensitivity reactions may manifest as severe intraocular inflammation. **Side Effects:** The following adverse reactions are discussed Endophthalmitis and Retinal Detachments, Increases in Intraocular Pressure, Thromboembolic Events, Fatal Events in DME Patients	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	aap) Basiliximab 10mg/Vial lyophilized powder for Injection Basiliximab In-house10mg/Vial **Immune Suppressant**	Basiliximab is indicated for the prophylaxis of acute organ rejection in patients receiving renal transplantation when used as part of an immunosuppressive regimen that includes cyclosporine, USP (MODIFIED) and corticosteroids. The efficacy of Basiliximab (basiliximab) for the prophylaxis of acute rejection in recipients of other solid organ allografts has not been demonstrated.	**Contraindications:** Basiliximab (basiliximab) is contraindicated in patients with known hypersensitivity to basiliximab or any other component of the formulation. **Side Effects:** The following adverse events occurred in ≥ 10% of Basiliximab (basiliximab) -treated patients: *Gastrointestinal System:* constipation, nausea, abdominal pain, vomiting, diarrhea, dyspepsia; *Body as a Whole-General:* pain, peripheral edema, fever, viral infection; *Metabolic and Nutritional:* hyperkalemia, hypokalemia, hyperglycemia, hypercholesterolemia, hypophosphatemia, hyperuricemia; *Urinary System:* urinary tract infection; *Respiratory System:* dyspnea, upper respiratory tract infection; *Skin and Appendages:* surgical wound complications, acne; *Cardiovascular Disorders-General:* hypertension; *Central and Peripheral Nervous System:* headache, tremor; Psychiatric: insomnia; *Red Blood Cell:* anemia.	20 mg/vial	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
	Incepta Pharmaceuticals Limited	aaq) Cetuximab 200mg/100ml Vial Injection Cetuximab In-House 200mg/100ml Vial **Antineoplastic Agent**	<u>Squamous Cell Carcinoma of the Head and Neck (SCCHN)</u> Cetuximab is indicated in combination with radiation therapy for the initial treatment of locally or regionally advanced squamous cell carcinoma of the head and neck. Cetuximab is indicated in combination with platinum-based therapy with 5-FU for the firstline treatment of patients with recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck. Cetuximab, as a single agent, is indicated for the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck for	**Contraindications:** None **Side Effects:** The following adverse reactions are discussed in greater detail in other sections of the label: - Infusion reactions - Cardiopulmonary arrest - Pulmonary toxicity - Dermatologic toxicity - Hypomagnesemia and Electrolyte Abnormalities	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

			whom prior platinum-based therapy has failed. <u>K-Ras Mutation-negative, EGFR-expressing Colorectal Cancer</u> Cetuximab is indicated for the treatment of K-Ras mutation-negative (wild-type), epidermal growth factor receptor (EGFR)-expressing, metastatic colorectal cancer (mCRC) as determined by FDA-approved tests for this use - In combination with FOLFIRI (irinotecan, 5-fluorouracil, leucovorin) for firstline treatment, - in combination with irinotecan in patients who are refractory to irinotecanbased chemotherapy, - as a single agent in patients who have failed oxaliplatin- and irinotecan-based chemotherapy or who are intolerant to irinotecan.					
		aar) Ipilimumab 200mg/ 40ml Vial Injection Ipilimumab In-House 200mg/40ml **Anticancer**	Ipilimumab is indicated for the treatment of unresectable or metastatic melanoma.	**Contraindications:** None **Side Effects:** The following adverse reactions are discussed in greater detail in other sections of the labeling. • Immune-mediated enterocolitis. • Immune-mediated hepatitis. • Immune-mediated dermatitis. • Immune-mediated neuropathies. • Immune-mediated endocrinopathies. Other immune-mediated adverse reactions, including ocular manifestations	New	USFDA	*Abyjgv`b Kiv †h‡Z cv‡i |*	*Abyjgv`b Kiv nj |*

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	Aas) Ipilimumab 50mg/ 10ml Vial Injection Ipilimumab In-House 50mg/10ml **Anticancer**	Ipilimumab is indicated for the treatment of unresectable or metastatic melanoma.	**Contraindications:** None **Side Effects:** The following adverse reactions are discussed in greater detail in other sections of the labeling. • Immune-mediated enterocolitis. • Immune-mediated hepatitis. • Immune-mediated dermatitis. • Immune-mediated neuropathies. • Immune-mediated endocrinopathies. Other immune-mediated adverse reactions, including ocular manifestations	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		aas) Tedizolid Phosphate 200mg Tablet Tedizolid Phosphate In-house 200 mg **Antibacterial**	Tedizolid is an oxazolidinone-class antibacterial drug indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Tedizolid and other antibacterial drugs. Tedizolid should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.	**Contraindications:** None **Side Effects:** The most common adverse reactions (>2%) are nausea, headache, diarrhea, vomiting, and dizziness.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		aat) Tedizolid Phosphate 200mg/Vial lyophilized powder for Injection Tedizolid Phosphate In-house 200 mg/Vial **Antibacterial**	Tedizolid is an oxazolidinone-class antibacterial drug indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Tedizolid and other antibacterial drugs. Tedizolid should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.	**Contraindications:** None **Side Effects:** The most common adverse reactions (>2%) are nausea, headache, diarrhea, vomiting, and dizziness.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	aau) Hydroxyzine Hydrochloride 50mg Tablet Hydroxyzine Hydrochloride BP 50mg **Antianxiety**	Symptomatic relief of anxiety and tension associated with psychoneurosis; adjunct therapy in organic disease states with anxiety; management of pruritus caused by allergic conditions; sedative before and after general anesthesia (PO, IM).	**Contraindications**: Early pregnancy; hypersensitivity to hydroxyzine or cetirizine **Side Effects:** Cardiovascular: Chest tightness. CNS: Transitory drowsiness; involuntary motor activity, including tremor and convulsions. GI: Dry mouth. Respiratory: Hypersensitivity reactions (eg, wheezing, shortness of breath).	10mg and 25mg Tablet; 10mg/5ml suspension	USFDA	c‡qvRb †bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb †bB wea‡q Av‡e`b bvgÄyK iv nj
		aav) Empagliflozin 10mg Tablet Empagliflozin In house 10mg **Antidiabetic**	Empagliflozin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Limitation of Use:** Empagliflozin is not recommended for patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.	**Contraindications:** History of serious hypersensitivity reaction to Empagliflozin. Severe renal impairment, end-stage renal disease, or dialysis **Side Effects:** The following important adverse reactions are described below and elsewhere in the labeling: Hypotension, Impairment in Renal Function, Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues, Genital Mycotic Infections, Urinary Tract Infections, Increased Low-Density Lipoprotein Cholesterol (LDL-C)	New	USFDA	c‡qvRb †bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb †bB wea‡q Av‡e`b bvgÄyK iv nj
		aaw) Empagliflozin 25mg Tablet Empagliflozin In house 25mg **Antidiabetic**	Do	Do	New	USFDA	c‡qvRb †bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb †bB wea‡q Av‡e`b bvgÄyK iv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	aax) Colistimethate 150mg/Vial Injection Colistimethate Sodium USP 384.6154mg eq. to Colistimethate 150mg/Vial **Antibiotic**	Colistimethate sodium Parenteral is indicated for the treatment of acute or chronic infections due to sensitive strains of certain gram-negative bacilli. It is particularly indicated when the infection is caused by sensitive strains of Pseudomonas aeruginosa. This antibiotic is not indicated for infections due to Proteus or Neisseria. Colistimethate sodium Parenteral has proven clinically effective in treatment of infections due to the following gram-negative organisms: Enterobacter aerogenes, Escherichia coli, Klebsiella pneumoniae and Pseudomonas aeruginosa. Colistimethate sodium Parenteral may be used to initiate therapy in serious infections that are suspected to be due to gram-negative organisms and in the treatment of infections due to susceptible gram-negative pathogenic bacilli. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Colistimethate sodium and other antibacterial drugs, Colistimethate sodium should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.	**Contraindications:** The use of Colistimethate sodium Parenteral is contraindicated for patients with a history of sensitivity to the drug or any of its components. **Side Effects:** The following adverse reactions have been reported: *Gastrointestinal:* gastrointestinal upset *Nervous System:* tingling of extremities and tongue, slurred speech, dizziness, vertigo and paresthesia *Integumentary:* generalized itching, urticaria and rash *Body as a Whole:* fever *Laboratory Deviations:* increased blood urea nitrogen (BUN), elevated creatinine and decreased creatinine clearance *Respiratory System:* respiratory distress and apnea *Renal System:* nephrotoxicity and decreased urine output	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg		wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	aay)	Polymyxin B 500,000 units powder for injection per vial Polymyxin B Sulfate USP 83.34mg eq. to Polymyxin B 5,00,000 units **Antibiotic**	- Susceptible infections - Ocular infections - Otic infections - Skin infections	**Contraindications:** Hypersensitivity, perforated ear drums **Side Effects:** Dizziness, paraesthesia, muscle weakness, ataxia, confusion, drowsiness, psychoses, convulsions, coma. Neuromuscular blockade characterized by respiratory paralysis and apoea. Acute interstitial nephritis; nausea, vomiting, electrolyte imbalance. Topical: Hypersensitivity eg, macular rashes, risk of systemic toxicity if applied to large areas of broken skin. Otic: Ototoxicity, stinging and burning sensation. Ophthalmic: Hypersensitivity, itching, redness and oedema of conjunctiva and eye lid. Intrathecal: Meningeal irritation. Potentially Fatal: Nephrotoxicity (higher doses and preexisting failure), neurotoxicity; resp failure; anaphylaxis.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		aaz)	Salbutamol 5mg/5ml Ampoule Injection Salbutamol Sulphate BP 6mg eq. to Salbutamol 5mg/5ml **Bronchodialator; Adreneceptor Agonist**	Salbutamol I.V. infusion solution is indicated for: • the relief of severe bronchospasm associated with acute exacerbations of chronic bronchitis and bronchial asthma, • The treatment of status asthmaticus. In many patients, salbutamol infusion solution will be no more effective, and likely less well tolerated, than SALBUTAMOL HFA inhalation aerosol or SALBUTAMOL respirator solution. However, patients who are severely ill with airway inflammation and mucus plugging may respond well to parenteral salbutamol after failing to benefit from the inhaled drug. This product should be administered under the supervision of a qualified health professional who is experienced in the use of parenteral	**Contraindications:** • Patients who are hypersensitive to this drug or to any ingredient in the formulation or component of the container • Patients with cardiac tachyarrhythmias • Patients at risk of threatened abortion during the first or second trimester **Side Effects:** Fine muscle tremor is a common side effect of SALBUTAMOL infusion solution. This is due to direct beta2-stimulation by salbutamol of skeletal muscle. There have been very rare reports of transient muscle cramps. A dose-dependent increase in heart rate, secondary to a reduction in peripheral resistance, due to vasodilation, may occur with parenteral salbutamol, and may cause palpitations. This is most likely to occur in patients with normal heart rates. In patients with pre-existing sinus tachycardia, especially those in status asthmaticus, the heart rate tends to fall as the condition of	2/4/8mg Tablet 100/200mcg Capsule 5mg/ml, 5mg/2.5ml Nebulizer Solution	BNF 67 Page: 186	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

			preparations and in the management of asthma. Appropriate management of therapy and complications is only possible when adequate diagnostic and treatment facilities are readily available.	the patient improves. Cardiac arrhythmias (including atrial fibrillation, supraventricular tachycardia and extrasystoles) have been reported, usually in susceptible patients. In the management of pre-term labour, salbutamol solution for infusion has uncommonly been associated with pulmonary edema and myocardial ischaemia. Patients with predisposing factors including multiple pregnancies, fluid overload, maternal infection and pre-eclampsia may have an increased risk of developing pulmonary edema. Paradoxical bronchospasm has been reported to occur following salbutamol inhalation therapy, requiring the immediate discontinuation of the drug and the institution of alternative forms of therapy. As with other beta2-agonists, hyperactivity has been reported rarely in children. Potentially serious hypokalemia may result from beta2-agonist therapy, mainly from parenteral and nebulised administration. Other side effects which may occur with salbutamol are sweating, headache, dizziness, flushing, nausea, vomiting, muscle cramps, insomnia, drowsiness, restlessness, irritability, chest discomfort, difficulty in micturition, hypertension, angina, vertigo, central nervous system stimulation, unusual taste and drying or irritation of the oropharynx. Immediate hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension, rash, oropharyngeal oedema, anaphylaxis and collapse have been reported very rarely. Lactic acidosis has also been reported very rarely in patients receiving intravenous salbutamol therapy for the treatment of acute asthma exacerbation				

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	aab) Salbutamol 500mcg/ml Injection Salbutamol Sulphate BP 600mcg eq. to Salbutamol 500mcg/ml **Bronchodialator; Adreneceptor Agonist**	Salbutamol BP is a beta-adrenergic stimulant that has a selective action on the beta2-adrenoceptors in the bronchi and uterus and much less action on the beta1-adrenoceptors in the heart. - Salbutamol parenteral preparations are indicated for two distinct clinical situations under the direction of a physician: - For the relief of severe bronchospasm associated with asthma or bronchitis and for the management of status asthmaticus. - For the management of premature labour uncomplicated by conditions such as placenta praevia, ante-partum haemorrhage or toxaemia of pregnancy, in the last trimester of pregnancy	**Contraindications:** - Salbutamol parenteral preparations are contra-indicated in patients with a history of hypersensitivity to any of their components. - Although intravenous salbutamol is used in the management of premature labour, uncomplicated by conditions such as placenta praevia, ante-partum haemorrhage or toxaemia of pregnancy, salbutamol presentations should not be used for threatened abortion. - Salbutamol should not be used as a tocolytic agent in patients with pre-existing ischaemic heart disease or those patients with significant risk factors for ischaemic heart disease. **Side Effects:** Adverse events are listed below by system organ class and frequency. Frequencies are defined as: very common (≥1/10), common (≥ 1/100 and < 1/10), uncommon (≥1/1000 and <1/100), rare (≥1/10,000 and <1/1000) and very rare (<1/10,000) including isolated reports. Very common and common events were generally determined from clinical trial data. Rare and very rare events were generally determined from spontaneous data. Immune system disorders Very rare: Hypersensitivity reactions including angioedema, urticaria,bronchospasm, hypotension and collapse. Metabolism and nutrition disorders Rare: Hypokalaemia. Potentially serious hypokalaemia may result from beta-2 agonist therapy. Very rare: Lactic acidosis Lactic acidosis has been reported very rarely in patients receiving intravenous and nebulised salbutamol therapy for the treatment of acute asthma exacerbation. Nervous system disorders	2/4/8mg Tablet 100/200mcg Capsule 5mg/ml, 5mg/2.5ml Nebulizer Solution	BNF 67 Page: 186	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

				Very common: Tremor. Common: Headache. Very rare: Hyperactivity. <u>Cardiac disorder</u> Very common: Tachycardia, palpitations. Rare: Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles. <u>Respiratory indication</u> Uncommon: Myocardial ischaemia. <u>Obstetric indication</u> Unknown: Myocardial ischaemia <u>Vascular disorders:</u> Rare: Peripheral vasodilatation. <u>Respiratory, thoracic and mediastinal disorders:</u> Uncommon: Pulmonary oedema. In the management of pre-term labour, salbutamol injection/solution for infusion have uncommonly been associated with pulmonary oedema. Patients with predisposing factors including multiple pregnancies,fluid overload, maternal infection and pre-eclampsia may have an increased risk of developing pulmonary oedema. <u>Gastrointestinal disorders</u> Very rare: Nausea, vomiting. In the management of premature labour, intravenous infusion of salbutamol has very rarely been associated with nausea and vomiting. <u>Musculoskeletal and connective tissue disorders</u> Common: Muscle cramps. <u>Injury, poisoning and procedural complications</u> Very rare: Slight pain or stinging on i.m. use of undiluted injection				

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg		wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited	Aaad)	Acetylcysteine 200mg Effervescent Tablet N-Acetylcysteine USP 200mg **Mucolytic Agent**	N-acetylcysteine is used as a mucolytic, of non-infective secretions in cystic fibrosis and in respiratory conditions. N-acetylcysteine is an effective antidote in paracetamol overdosage	**Contraindications:** Hypersensitivity to N-acetylcysteine. Safety in pregnancy has not been established. **Side Effects:** Adverse effects include bronchospasm, nausea, vomiting, stomatitis, rhinorrhoea, headache, tinnitus, urticaria, chills and fever. Anaphylaxis has less frequently been reported.	200mg/Sachet Effervescent Granules 600mg effervescent Tablet 300mg/3ml Nebulizer Solution 0.1gm/0.2gm/0.60gm Powder for Suspension/Sachet		Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
06	Incepta Pharmaceuticals Limited (Dhamrai Unit)	a)	Calcium phosphate 250mg + Vitamin D3 (as Colecalciferol) 250 IU Chewable tablet Calcium Phosphate BP 715mg eq. to Elemental Calcium 250mg + Dry Vitamin D3 100 In house 2.5mg eq. to Colecalciferol 250 IU **Vitamin + Minerals**	• Treating or preventing calcium deficiency. It may also be used for other conditions as determined by your doctor. • Calcium phosphate & vitamin Combination is a dietary supplement. It works by providing extra calcium to the body.	**Contraindications:** -If you are allergic to any ingredient in Calcium phosphate & vitamin Combination -If you have high blood calcium levels or high blood vitamin D levels -you take aluminum salts (eg, aluminum chloride) **Side Effects:** Common side effects may include: Constipation; headache severe side effects: Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); loss of appetite; nausea; severe or persistent constipation; vomiting.	New		c‡qvRb †bB weavq Av‡e`b bvgÄyÿ Kiv †h‡Z cv‡i	c‡qvRb †bB weavq Av‡e`b bvgÄyÿ Kiv nj
		b)	Calcium 500mg + Vitamin D3 (as Colecalciferol) 500 IU Chewable tablet Calcium Phosphate BP 1430.00 mg eq. to Elemental Calcium 500mg + Dry Vitamin D3 100 In house 5mg eq. to Colecalciferol 500 IU **Vitamin + Minerals**	• Treating or preventing calcium deficiency. It may also be used for other conditions as determined by your doctor. • Calcium phosphate & vitamin Combination is a dietary supplement. It works by providing extra calcium to the body.	**Contraindications:** -If you are allergic to any ingredient in Calcium phosphate & vitamin Combination -If you have high blood calcium levels or high blood vitamin D levels -you take aluminum salts (eg, aluminum chloride) **Side Effects:** Common side effects may include: Constipation; headache severe side effects: Severe allergic reactions (rash; hives; itching; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); loss of appetite; nausea; severe or persistent constipation; vomiting.	Calcium 500mg + Vitamin D3 200 IU tablet Calcium 600mg + Vitamin D3 400 IU tablet		c‡qvRb †bB weavq Av‡e`b bvgÄyÿ Kiv †h‡Z cv‡i	c‡qvRb †bB weavq Av‡e`b bvgÄyÿ Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited (Dhamrai Unit)	c) Calcium 250mg + Vitamin D3 250 IU Gummy Tablet Calcium Phosphate BP 715mg eq. to Elemental Calcium 250mg + Dry Vitamin D3 100 In house 2.5mg eq. to Colecalciferol 250 IU **Vitamin + Minerals**	• Calcium is necessary for many normal functions of your body, especially bone formation and maintenance. • Vitamin D is important for the absorption of calcium from the stomach and for the functioning of calcium in the body. • Calcium and vitamin D combination is used to prevent or to treat a calcium deficiency	**Contraindications:** None **Side Effects:** Common side effects may include: • an irregular heartbeat; • nausea, constipation; • weakness, drowsiness, headache; • dry mouth, or a metallic taste in your mouth; or • Muscle or bone pain.	Calcium 500mg + Vitamin D3 200 IU tablet Calcium 600mg + Vitamin D3 400 IU tablet		Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
		d) Calcium Phosphate 500mg + Vitamin D3 500 IU Gummy Tablet Calcium Phosphate BP 1430.00 mg eq. to Elemental Calcium 500mg + Dry Vitamin D3 100 In house 5mg eq. to Colecalciferol 500 IU **Vitamin + Minerals**	• Calcium is necessary for many normal functions of your body, especially bone formation and maintenance. • Vitamin D is important for the absorption of calcium from the stomach and for the functioning of calcium in the body. • Calcium and vitamin D combination is used to prevent or to treat a calcium deficiency	Contraindications: None Side Effects: Common side effects may include: • an irregular heartbeat; • nausea, constipation; • weakness, drowsiness, headache; • dry mouth, or a metallic taste in your mouth; or • Muscle or bone pain.	Calcium 500mg + Vitamin D3 200 IU tablet Calcium 600mg + Vitamin D3 400 IU tablet		Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
		e) Calcium Phosphate 87.5mg + Vitamin D3 100 IU Gummy Tablet Calcium Phosphate BP 250.25mg eq. to Elemental Calcium 87.50mg + Dry Vitamin D3 100 In house 1mg eq. to Colecalciferol 100 IU **Vitamin + Minerals**	• Calcium is necessary for many normal functions of your body, especially bone formation and maintenance. • Vitamin D is important for the absorption of calcium from the stomach and for the functioning of calcium in the body. • Calcium and vitamin D combination is used to prevent or to treat a calcium deficiency	**Contraindications:** None Side Effects: Common side effects may include: • an irregular heartbeat; • nausea, constipation; • weakness, drowsiness, headache; • dry mouth, or a metallic taste in your mouth; or • Muscle or bone pain.	Calcium 500mg + Vitamin D3 200 IU tablet Calcium 600mg + Vitamin D3 400 IU tablet		c‡qvRb †bB wea\q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb †bB wea\q Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Limited (Dhamrai Unit)	f) Vitamin D3 (as cholecalciferol) 1000 IU gummy tablet Dry Vitamin D3 100 In house 10.0mg eq. to cholecalciferol BP 1000 IU **Vitamin**	Cholecalciferol is used to treat or prevent many conditions caused by a lack of vitamin D, especially conditions of the skin or bones.	**Contraindications:** None **Side Effects:** signs of an allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue, or throat. Stop taking cholecalciferol and call your doctor at once if you have: • thinking problems, changes in behavior, feeling irritable; • urinating more than usual; • chest pain, feeling short of breath; or • early signs of vitamin D overdose (weakness, metallic taste in your mouth, weight loss, muscle or bone pain, constipation, nausea, and vomiting).	1000 IU Tablet		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		g) Cyanocobalamin 250 mcg Gummy Tablet Cyanocobalamin BP 250 mcg **Vitamin**	Cyanocobalamin is indicated for vitamin B12 deficiencies due to malabsorption which may be associated with the following conditions: • Addisonian (pernicious) anemia • Gastrointestinal pathology, dysfunction, or surgery, including gluten enteropathy or sprue, small bowel bacteria overgrowth, total or partial gastrectomy • Fish tapeworm infestation • Malignancy of pancreas or bowel • Folic acid deficiency It may be possible to treat the underlying disease by surgical correction of anatomic lesions leading to small bowel bacterial overgrowth, expulsion of fish tapeworm, discontinuation of drugs leading to vitamin malabsorption (see Drug Interactions), use of a gluten-free diet in nontropical sprue, or administration of antibiotics in tropical sprue. Such measures remove the need for long-term administration of Cyanocobalamin. Requirements of vitamin B12 in excess of normal (due to pregnancy, thyrotoxicosis, hemolytic anemia, hemorrhage, malignancy, hepatic and renal disease) can usually be met with oral supplementation.	**Contraindications:** Sensitivity to cobalt and/or vitamin B12 is a contraindication. **Side Effects:** Cardiovascular: Pulmonary edema and congestive heart failure early in treatment; peripheral vascular thrombosis. Hematological: Polycythemia vera Gastrointestinal: Mild transient diarrhea; Dermatological: Itching; transitory exanthema; Miscellaneous: Feeling of swelling of entire body	New		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
07	Ziska Pharmaceuticals Ltd.	a) Bivalirudin 250mg/5ml Vial Injection Bivalirudin Trifluroacetate hydrate INN 263.19mg eq. to 250mg/5ml **Anticoagulant**	Bivalirudin is a direct thrombin inhibitor indicated for use as an anticoagulant in patients: With unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA). Undergoing percutaneous coronary intervention (PCI) with provisional use of glycoprotein IIb/IIIa inhibitor (GPI) as in the REPLACE-2 study. With, or at risk of, heparin-induced thrombocytopenia (HIT) or heparin-induced thrombocytopenia and thrombosis syndrome (HITTS), undergoing PCI. Angiomax is intended for use with aspirin. **Limitation of use**: Safety and effectiveness not established in patients with acute coronary syndromes who are not undergoing PTCA or PCI.	**Contraindications:** Active major bleeding, Hypersensitivity to bivalirudin or any product components **Side effects:** Most common adverse reaction was bleeding (28%). Other adverse reactions (incidence >0.5%) were headache, thrombocytopenia and fever.	New	USFDA	*Abyjgv`b Kiv †h‡Z cv‡i |*	*Abyjgv`b Kiv nj |*
		b) Methyl Prednisolone 32 mg Tablet Methyl Prednisolone USP 32mg **Glucocorticoid**	It is indicated in the following conditions: **Endocrine Disorders** Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the first choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable; in infancy mineralocorticoid supplementation is of particular importance): Congenital adrenal hyperplasia, Nonsuppurative thyroiditis, Hypercalcaemia associated with cancer ***Rheumatic Disorders*** As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)	**Contraindications:** Systemic fungal infections and known hypersensitivity to components. **Side effects:** *Fluid and Electrolyte Disturbances* Sodium retention, Congestive heart failure in susceptible patients, Hypertension, Fluid retention, Potassium loss,Hypokalemic alkalosis *Musculoskeletal* Muscle weakness, Loss of muscle mass Steroid myopathy Osteoporosis, Tendon rupture, particularly of the Achilles tendon, Vertebral compression fractures, Aseptic necrosis of femoral and humeral heads, Pathologic fracture of long bones *Gastrointestinal* Peptic ulcer with possible perforation and hemorrhage, Pancreatitis, Abdominal distention, Ulcerative, esophagitis, Increases in alanine transaminase (ALT, SGPT), aspartate transaminase (AST, SGOT), and alkaline phosphatase have been observed following corticosteroid treatment. These changes are usually small, not associated with any clinical	2mg, 4mg & 16mg Tablet	USFDA	*c‡qvRb †bB wea\q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |*	*c‡qvRb †bB wea\q Av‡e`b bvgÄyi Kiv nj |*

			Ankylosing spondylitis, Acute and subacute bursitis, Acute nonspecific tenosynovitis, Acute gouty arthritis, Post-traumatic osteoarthritis, Synovitis of osteoarthritis, Epicondylitis ***Collagen Diseases*** During an exacerbation or as maintenance therapy in selected cases of: Systemic lupus erythematosus, Systemic dermatomyositis (polymyositis), Acute rheumatic carditis ***Dermatologic Diseases*** Pemphigus, Bullous dermatitis herpetiformis, Severe erythema multiforme (Stevens-Johnson syndrome), Exfoliative dermatitis, Mycosis fungoides, Severe psoriasis, Severe seborrhoeic dermatitis ***Allergic States*** Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment: Seasonal or perennial allergic rhinitis, Serum sickness, Bronchial asthma, Drug hypersensitivity reactions, Contact dermatitis, Atopic dermatitis ***Ophthalmic Diseases*** Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: Allergic corneal marginal ulcers, Herpes zoster ophthalmicus • Anterior segment inflammation •Diffuse posterior uveitis and choroiditis • Sympathetic ophthalmia • Allergic conjunctivitis • Keratitis • Chorioretinitis • Optic neuritis • Iritis and iridocyclitis ***Respiratory Diseases*** • Symptomatic sarcoidosis •Loeffler's syndrome not manageable by other means • Berylliosis •Fulminating or disseminated pulmonary tuberculosis when used	syndrome and are reversible upon discontinuation. *Dermatologic* Impaired wound healing, Petechiae and ecchymoses May suppress reactions to skin tests. Thin fragile skin Facial erythema Increased sweating *Neurological* Increased intracranial pressure with papilledema (pseudo-tumor cerebri) usually after treatment Convulsions, Vertigo, Headache, *Endocrine* Development of Cushingoid state Suppression of growth in children Secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness Menstrual irregularities Decreased carbohydrate tolerance Manifestations of latent diabetes mellitus Increased requirements of insulin or oral hypoglycemic agents in diabetics *Ophthalmic* Posterior subcapsular cataracts, Increased intraocular pressure Glaucoma, Exophthalmos *Metabolic* Negative nitrogen balance due to protein catabolism				

			concurrently with appropriate antituberculous chemotherapy • Aspiration pneumonitis ***Haematologic Disorders*** •Idiopathic thrombocytopenia purpura in adults •Secondary thrombocytopenia in adults • Acquired (autoimmune) haemolytic anaemia • Erythroblastopenia (RBC anaemia) • Congenital (erythroid) hypoplastic anaemia ***Neoplastic Diseases*** For palliative management of: •Leukemias and lymphomas in adults • Acute leukaemia of childhood ***Edematous States*** To induce a diuresis or remission of proteinuria in the nephritic syndrome, without uraemia, of the idiopathic type or that due to lupus erythematosus. ***Gastrointestinal Diseases*** To tide the patient over a critical period of the disease in: Ulcerative colitis, Regional enteritis ***Nervous System*** Acute exacerbations of multiple sclerosis ***Miscellaneous*** Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate antituberculous chemotherapy • Trichinosis with neurologic or myocardial involvement.				

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Ziska Pharmaceuticals Ltd.	c) Canagliflozin 50 mg + Metformin HCl 500 mg Tablet Canagliflozin Hemihydrate INN 51.00 mg eq.to 50.00 mg Canagliflozin + Metformin HCl 500 mg BP **Antidiabetic**	It is a sodium-glucose co-transporter 2 (SGLT2) inhibitor and biguanide combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing metformin or canagliflozin or in patients already being treated with both canagliflozin and metformin. **Limitation of use:** Not for treatment of type 1 diabetes or diabetic ketoacidosis	Contraindications: Renal impairment, ESRD, or on dialysis. Metabolic acidosis, including diabetic ketoacidosis, History of serious hypersensitivity reaction to canagliflozin or metformin. Side effects: Most common adverse reactions associated with canagliflozin (5% or greater incidence): female genital mycotic infections, urinary tract infection, and increased urination Most common adverse reactions associated with metformin (5% or greater incidence) are diarrhea, nausea, vomiting, flatulence, asthenia, indigestion, abdominal discomfort, and headache. WARNING: LACTIC ACIDOSIS *See full prescribing information for complete boxed warning.* -Lactic acidosis can occur due to metformin accumulation. The risk increases with conditions such as renal impairment, sepsis, dehydration, excess alcohol intake, hepatic impairment, and acute congestive heart failure -Symptoms include malaise, myalgias, respiratory distress, increasing somnolence, and nonspecific abdominal distress. Laboratory abnormalities include low pH, increased anion gap, and elevated blood lactate -If acidosis is suspected, discontinue INVOKAMET and hospitalize the patient immediately	Canagliflozin 100mg Tablet Metformin HCl 500mg Tablet	USFDA	c‡qvRb †bB wea‡q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb †bB wea‡q Av‡e`b bvgÄyi Kiv nj
		d) Canagliflozin 50 mg + Metformin HCl 1000 mg Tablet Canagliflozin Hemihydrate INN 51.00 mg eq.to 50.00 mg Canagliflozin + Metformin HCl 1000 mg BP **Antidiabetic**	-do-	-do-	Canagliflozin 100mg Tablet Metformin HCl 1000mg Tablet	USFDA	c‡qvRb †bB wea‡q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb †bB wea‡q Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Ziska Pharmaceuticals Ltd.	e) Canagliflozin 150 mg + Metformin HCl 500 mg Tablet Canagliflozin Hemihydrate INN 153.00 mg eq.to 150.00 mg Canagliflozin + Metformin HCl 500 mg BP **Antidiabetic**	Do	Do	Canagliflozin 100mg Tablet Metformin HCl 500mg Tablet	USFDA	c‡qvRb †bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i |	c‡qvRb †bB wea‡q Av‡e`b bvgÄyK iv nj |
		f) Canagliflozin 150 mg + Metformin HCl 1000 mg Tablet Canagliflozin Hemihydrate INN 153.00 mg eq.to 150.00 mg Canagliflozin + Metformin HCl 1000 mg BP **Antidiabetic**	Do	Do	Canagliflozin 100mg Tablet Metformin HCl 1000mg Tablet	USFDA	c‡qvRb †bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i |	c‡qvRb †bB wea‡q Av‡e`b bvgÄyK iv nj |
		g) Ulipristal Acetate 5 mg Tablet Ulipristal Acetate INN 5 mg **Steriod Hormone**	Ulipristal acetate is indicated for pre-operative treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age.	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Pregnancy and breastfeeding. Genital bleeding of unknown aetiology or for reasons other than uterine fibroids. Uterine, cervical, ovarian or breast cancer. **Side effects:** nausea, abdominal pain, oedema, hot flushes, headache, dizziness, malaise, menstrual disturbances, uterine haemorrhage, endometrial thickening, ovarian cyst (including rupture), breast pain, pelvic pain, myalgia, acne, hyperhidrosis; less commonly dyspepsia, dry mouth, flatulence, constipation, epistaxis, anxiety, urinary incontinence.	30mg Tablet	BNF-67	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Ziska Pharmaceuticals Ltd.	h) Methoxsalen 10 mg Capsule Methoxsalen USP 10 mg **Antipsoriatic**	Photochemotherapy (methoxsalen with long wave UVA radiation) is indicated for the symptomatic control of severe, recalcitrant, disabling psoriasis not adequately responsive to other forms of therapy and when the diagnosis has been supported by biopsy. Photochemotherapy is intended to be administered only in conjunction with a schedule of controlled doses of long wave ultraviolet radiation. Photochemotherapy (methoxsalen with long wave ultraviolet radiation) is indicated for the repigmentation of idiopathic vitiligo. Photopheresis (methoxsalen with long wave ultraviolet radiation of white blood cells) is indicated for use with the UVAR* System in the palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL) in persons who have not been responsive to other forms of treatment. While this dosage form of methoxsalen has been approved for use in combination with photopheresis, This Capsules have not been approved for that use.	**Contraindications:** Patients exhibiting idiosyncratic reactions to psoralen compounds. Patients possessing a specific history of light sensitive disease states should not initiate methoxsalen therapy. Diseases associated with photosensitivity include lupus erythematosus, porphyria cutanea tarda, erythropoietic protoporphyria, variegate porphyria, xeroderma pigmentosum, and albinism. Patients exhibiting melanoma or possessing a history of melanoma. Patients exhibiting invasive squamous cell carcinomas. Patients with aphakia, because of the significantly increased risk of retinal damage due to the absence of lenses. **Side effects:** The most commonly reported side effect of methoxsalen alone is nausea, which occurs with approximately 10% of all patients. This effect may be minimized or avoided by instructing the patient to take methoxsalen with milk or food, or to divide the dose into two portions, taken approximately one-half hour apart. Other effects include nervousness, insomnia, and psychological depression. **COMBINED METHOXSALEN/UVA THERAPY**: 1. PRURITUS: This adverse reaction occurs with approximately 10% of all patients. In most cases, pruritus can be alleviated with frequent application of bland emollients or other topical agents; severe pruritus may require systemic treatment. If pruritus is unresponsive to these measures, shield pruritic areas from further UVA exposure until the condition resolves. If intractable pruritus is generalized, UVA treatment should be discontinued until the pruritus disappears. 2. ERYTHEMA: Mild, transient erythema at 24–48 hours after PUVA therapy is an expected reaction and indicates that a therapeutic interaction between methoxsalen and UVA occurred. Any area showing moderate erythema (greater than Grade 2 — see Table 1 for grades of erythema) should	1gm/100ml Lotion	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

				be shielded during subsequent UVA exposures until the erythema has resolved. Erythema greater than Grade 2 which appears within 24 hours after UVA treatment may signal a potentially severe burn. Erythema may become progressively worse over the next 24 hours, since the peak erythemal reaction characteristically occurs 48 hours or later after methoxsalen ingestion. The patient should be protected from further UVA exposures and sunlight, and should be monitored closely. 3. **IMPORTANT DIFFERENCES BETWEEN PUVA ERYTHEMA AND SUNBURN:** PUVAinduced inflammation differs from sunburn or UVB phototherapy in several ways. The **in situ** depth of photochemistry is deeper within the tissue because UVA is transmitted further into the skin. The DNA lesions induced by PUVA are very different from UV-induced thymine dimers and may lead to a DNA crosslink. This DNA lesion may be more problematic to the cell because crosslinks are more lethal and psoralen-DNA photoproducts may be "new" or unfamiliar substrates for DNA repair enzymes. DNA synthesis is also suppressed longer after PUVA. The time course of delayed erythema is different with PUVA and may not involve the usual mediators seen in sunburn. PUVA-induced redness may be just beginning at 24 hours, when UVB erythema has already passed its peak. The erythema dose-response curve is also steeper for PUVA. Compared to equally erythemogenic doses of UVB, the histologic alterations induced by PUVA show more dermal vessel damage and longer duration of epidermal and dermal abnormalities. 4. **OTHER ADVERSE REACTIONS:** Those reported include edema, dizziness, headache, malaise, depression, hypopigmentation, vesiculation and bullae formation, non-specific rash, herpes simplex, miliaria, urticaria, folliculitis, gastrointestinal disturbances, cutaneous tenderness, leg cramps, hypotension, and extension of psoriasis.				

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Ziska Pharmaceuticals Ltd.	i) Sumatriptan 5 mg/100 µl unit dose aqueous Nasal Spray Sumatriptan Hemisulphate USP 11.66 mg e.q.to 5 mg Sumatriptan/100 µl unit dose **Antimigraine**	Sumatriptanis a serotonin (5-HT1B/1D) receptor agonist indicated for acute treatment of migraine with or without aura in adults. **Limitations of Use:** Use only if a clear diagnosis of migraine headache has been established. Not indicated for the prophylactic therapy of migraine attacks. Not indicated for the treatment of cluster headache.	**Contraindications:** History of coronary artery disease or coronary artery vasospasm; Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders; History of stroke, transient ischemic attack, or hemiplegic or basilar migraine; Peripheral vascular disease; Ischemic bowel disease; Uncontrolled hypertension; Recent (within 24 hours) use of another 5-HT1 agonist (e.g., another triptan) or of an ergotamine-containing medication; Concurrent or recent (past 2 weeks) use of monoamine oxidase-A inhibitor. Hypersensitivity to Sumatriptan (angioedema and anaphylaxis seen), Severe hepatic impairment **Side effects:** Most common adverse reactions (≥1% and >placebo) were burning sensation, disorder/discomfort of nasal cavity/sinuses, throat discomfort, nausea and/or vomiting, bad/unusual taste, and dizziness/vertigo.	50mg and 100mg Tablet	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		j) Sumatriptan 20 mg/ 100µl unit dose aqueous Nasal Spray Sumatriptan Hemisulphate USP 46.64 mg e.q.to 20 mg Sumatriptan/100µl unit dose **Antimigraine**	Sumatriptanis a serotonin (5-HT1B/1D) receptor agonist indicated for acute treatment of migraine with or without aura in adults. **Limitations of Use:** Use only if a clear diagnosis of migraine headache has been established. Not indicated for the prophylactic therapy of migraine attacks. Not indicated for the treatment of cluster headache.	**Contraindications:** History of coronary artery disease or coronary artery vasospasm; Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders; History of stroke, transient ischemic attack, or hemiplegic or basilar migraine; Peripheral vascular disease; Ischemic bowel disease; Uncontrolled hypertension; Recent (within 24 hours) use of another 5-HT1 agonist (e.g., another triptan) or of an ergotamine-containing medication; Concurrent or recent (past 2 weeks) use of monoamine oxidase-A inhibitor. Hypersensitivity to Sumatriptan (angioedema and anaphylaxis seen), Severe hepatic impairment **Side effects:** Most common adverse reactions (≥1% and >placebo) were burning sensation, disorder/discomfort of nasal cavity/sinuses, throat discomfort, nausea and/or vomiting, bad/unusual taste, and dizziness/vertigo.	50mg and 100mg Tablet	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Ziska Pharmaceuticals Ltd.	k) Dantrolene Sodium 50 mg Capsule Dantrolene Sodium USP 50mg **Skeletal Muscle Relaxant**	In Chronic Spasticity: Dantrolene is indicated in controlling the manifestations of clinical spasticity resulting from upper motor neuron disorders (e.g., spinal cord injury, stroke, cerebral palsy, or multiple sclerosis). It is of particular benefit to the patient whose functional rehabilitation has been retarded by the sequelae of spasticity. Such patients must have presumably reversible spasticity where relief of spasticity will aid in restoring residual function. **Dantrolene** is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders. If improvement occurs, it will ordinarily occur within the dosage titration and will be manifested by a decrease in the severity of spasticity and the ability to resume a daily function not quite attainable without **Dantrolene.** Occasionally, subtle but meaningful improvement in spasticity may occur with **Dantrolene** therapy. In such instances, information regarding improvement should be solicited from the patient and those who are in constant daily contact and attendance with him. Brief withdrawal of **Dantrolene** for a period of 2 to 4 days will frequently demonstrate exacerbation of the manifestations of spasticity and may serve to confirm a clinical	**Contraindications:** Active hepatic disease, such as hepatitis and cirrhosis, is a contraindication for use of Dantrolene. **Dantrolene** is contraindicated where spasticity is utilized to sustain upright posture and balance in locomotion or whenever spasticity is utilized to obtain or maintain increased function. **Side-effects:** The most frequently occurring side effects of Dantrolene have been drowsiness, dizziness, weakness, general malaise, fatigue, and diarrhea. These are generally transient, occurring early in treatment, and can often be obviated by beginning with a low dose and increasing dosage gradually until an optimal regimen is established. Diarrhea may be severe and may necessitate temporary withdrawal of Dantrolene therapy. If diarrhea recurs upon readministration of Dantrolene, therapy should probably be withdrawn permanently. Other less frequent side effects, listed according to system, are: **Gastrointestinal:** Constipation, rarely progressing to signs of intestinal obstruction, GI bleeding, anorexia, swallowing difficulty, gastric irritation, abdominal cramps, nausea and/or vomiting. **Hepatobiliary:** Hepatitis **Neurologic:** Speech disturbance, seizure, headache, light-headedness, visual disturbance, diplopia, alteration of taste, insomnia, drooling. **Cardiovascular:** Tachycardia, erratic blood pressure, phlebitis, heart failure. **Hematologic:** Aplastic anemia, anemia, leukopenia, lymphocytic lymphoma, thrombocytopenia. **Psychiatric:** Mental depression, mental confusion, increased nervousness. **Urogenital:** Increased urinary frequency, crystalluria, hematuria, difficult erection, urinary incontinence and/or nocturia, difficult urination and/or urinary retention.	25mg Capsule	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

			impression. A decision to continue the administration of **Dantrolene** on a long-term basis is justified if introduction of the drug into the patient's regimen: produces a significant reduction in painful and/or disabling spasticity such as clonus, or permits a significant reduction in the intensity and/or degree of nursing care required, or rids the patient of any annoying manifestation of spasticity considered important by the patient himself. **In Malignant Hyperthermia:** Oral **Dantrolene** is also indicated preoperatively to prevent or attenuate the development of signs of malignant hyperthermia in known, or strongly suspect, malignant hyperthermia susceptible patients who require anesthesia and/or surgery. Currently accepted clinical practices in the management of such patients must still be adhered to (careful monitoring for early signs of malignant hyperthermia, minimizing exposure to triggering mechanisms and prompt use of intravenous dantrolene sodium and indicated supportive measures should signs of malignant hyperthermia appear. Oral **Dantrolene** should be administered following a malignant hyperthermic crisis to prevent recurrence of the signs of malignant hyperthermia.	**Integumentary:** Abnormal hair growth, acne-like rash, pruritus, urticaria, eczematoid eruption, sweating. **Musculoskeletal:** Myalgia, backache. **Respiratory:** Feeling of suffocation, respiratory depression. **Special Senses:** Excessive tearing. **Hypersensitivity:** Pleural effusion with pericarditis, pleural effusion with associated eosinophilia, anaphylaxis. **Other:** Chills and fever. The published literature has included some reports of Dantrolene use in patients with Neuroleptic Malignant Syndrome (NMS). Dantrolene capsules are not indicated for the treatment of NMS and patients may expire despite treatment with **Dantrolene** capsules.				

bs	c¯ZKvi‡Ki bvg		JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Ziska Pharmaceuticals Ltd.	l)	Netupitant 300 mg + Palonosetron 0.5 mg Capsule Netupitant INN 300 mg + Palonosetron HCl INN 0.56 mg eq.to 0.50 mg Palonosetron **Antiemetic**	This is a fixed combination of netupitant, a substance P/neurokinin 1 (NK1) receptor antagonist, and palonosetron, a serotonin-3 (5-HT3) receptor antagonist indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Oral palonosetron prevents nausea and vomiting during the acute phase and netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.	**Contraindications:** None **Side-effects:** Most common adverse reactions (incidence ≥3% and greater than palonosetron) are headache, asthenia, dyspepsia, fatigue, constipation and erythema	Palonosetron 0.5 mg Capsule	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK iv †h‡Z cv‡i |	c‡qvRb †bB wea|q Av‡e`b bvgÄyK iv nj |
		m)	Triamcinolone Hexacetonide 5mg/ml vial Injection Triamcinolone Hexacetonide USP 5 mg/ml Vial **Adrenglucocorticoid**	The intralesional administration of triamcinolone hexacetonide injectable suspension,5 mg/mL is indicated for alopecia areata; discoid lupus erythematosus; keloids; localized hypertrophic, infiltrated, inflammatory lesions of granuloma annulare, lichen planus, lichen simplex chronicus (neurodermatitis), and psoriatic plaques; necrobiosis lipoidica diabeticorum. Aristospan may also be useful in cystic tumors of an aponeurosis or tendon (ganglia).	**Contraindications:** Triamcinolone Hexacetonide is contraindicated in patients who are hypersensitive to any components of this product. Intramuscular corticosteroid preparations are contraindicated for idiopathic thrombocytopenic purpura. **Side-effects:** **Allergic Reaction:** Anaphylactoid reactions, anaphylaxis, angioedema. **Cardiovascular:** Bradycardia, cardiac arrest, cardiac arrhythmias, cardiac enlargement, circulatory collapse, congestive heart failure, fat embolism, hypertension,hypertrophic cardiomyopathy in premature infants, myocardial rupture following recent myocardial infarction pulmonary edema, syncope,tachycardia, thromboembolism, thrombophlebitis, vasculitis. **Dermatologic:** Acne, allergic dermatitis, cutaneous and subcutaneous atrophy, dry scaly skin, ecchymoses and petechiae, edema, erythema, hyperpigmentation, hypopigmentation, impaired wound healing, increased sweating, rash, sterile abscess, striae, suppressed reactions to	Triamcinolone Acetonide 40mg/ml Injection	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK iv †h‡Z cv‡i |	c‡qvRb †bB wea|q Av‡e`b bvgÄyK iv nj |

				skin tests, thin fragile skin, thinning scalp hair, urticaria. **Endocrine:** Decreased carbohydrate and glucose tolerance, development of cushingoid state, glycosuria, hirsutism, hypertrichosis, increased requirements for insulin or oral hypoglycemic agents in diabetics, manifestations of latent diabetes mellitus, menstrual irregularities, secondary adrenocortical and pituitary unresponsiveness (particularly in times of stress, as in trauma, surgery, or illness), suppression of growth in pediatric patients. **Fluid and Electrolyte Disturbance:** Congestive heart failure in susceptible patients, fluid retention, hypokalemic alkalosis, potassium loss, sodium retention. **Gastrointestinal:** Abdominal distention, bowel/bladder dysfunction (after intrathecal administration), elevation in serum liver enzyme levels (usually reversible upon discontinuation), hepatomegaly, increased appetite, nausea, pancreatitis, peptic ulcer with possible perforation and hemorrhage, perforation of the small and large intestine (particularly in patients with inflammatory bowel disease), ulcerative esophagitis. **Metabolic:** Negative nitrogen balance due to protein catabolism. **Muskoskelatal:** Aseptic necrosis of femoral and humeral heads, calcinosis (following intra-articular or intralesional use), Charcot-like arthropathy, loss of muscle mass, muscle weakness, osteoporosis, pathologic fracture of long bones, postinjection flare (following intra-articular use), steroid myopathy, tendon rupture, vertebral compression fractures.				

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Ziska Pharmaceuticals Ltd.	n) Triamcinolone Hexacetonide 20mg/ml vial Injection Triamcinolone Hexacetonide USP 20 mg/ml **Adrenglucocorticoid**	Do	Do	Triamcinolone Acetonide 40mg/ml Injection	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		o) Aprepitant 125 mg Capsule Aprepitant INN 125 mg **Antiemetic**	Aprepitant is a substance P/neurokinin 1 (NK1) receptor antagonist, Indicated in combination with other antiemetic agents for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin , prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC), for the prevention of postoperative nausea and vomiting (PONV) **Limitations of Use:** Not studied for the treatment of established nausea and vomiting.Chronic continuous administration is not recommended.	**Contraindications:** Hypersensitivity to any component of this medication. • Aprepitant should not be used concurrently with pimozide, terfenadine, astemizole, or cisapride, since inhibition of CYP3A4 by aprepitant could result in elevated plasma concentrations of these drugs, potentially causing serious or life-threatening reactions **Side-effects:** Clinical adverse experiences for the CINV regimen in conjunction with highly and moderately emetogenic chemotherapy (incidence >10%) are: alopecia, anorexia, asthenia/fatigue, constipation, diarrhea, headache, hiccups, and nausea. Clinical adverse experiences for the PONV regimen (incidence >5%) are: constipation, hypotension, nausea, pruritus, pyrexia.	40mg Capsule	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Ziska Pharmaceuticals Ltd.	q) Colesevelam HCl 1.875gm/Sachet Powder for Oral Suspension Colesevelam HCl INN 1.875g/Sachet **Antihyperlipidemic**	Colesevelam is a bile acid sequestrant indicated as an adjunct to diet and exercise to reduce elevated low-density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia as monotherapy or in combination with a hydroxymethyl-glutaryl-coenzyme A (HMG CoA) reductase inhibitor (statin) , reduce LDL-C levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia as monotherapy or in combination with a statin after failing an adequate trial of diet therapy, improve glycemic control in adults with type 2 diabetes mellitus **Important Limitations of Use :** Do not use for glycemic control in type 1 diabetes or for treating Diabetic ketoacidosis. Colesevelam has not been studied in type 2 diabetes in combination with a dipeptidyl peptidase 4 inhibitor. Colesevelam has not been studied in Fredrickson Type I, III, IV, and V dyslipidemias. Colesevelam has not been studied in children younger than 10 years of age or in pre-menarchal girls.	**Contraindications:** Do not use in patients with a history of bowel obstruction. Do not use in patients with serum triglyceride (TG) concentrations >500 mg/dL. Do not use in patients with a history of hypertriglyceridemia-induced pancreatitis **Side-effects:** In clinical trials, the most common (incidence ≥2% and greater than placebo) adverse reactions with Colesevelam included constipation, dyspepsia, and nausea. Postmarketing reports with concomitant Colesevelam administration include: Increased seizure activity or decreased phenytoin levels in patients receiving phenytoin. Administer phenytoin 4 hours prior to Colesevelam, Reduced International Normalized Ratio (INR) in patients receiving warfarin. Monitor INR. Elevated thyroid-stimulating hormone (TSH) in patients receiving thyroid hormone replacement therapy. Administer thyroid hormones 4 hours prior to Colesevelam. Other postmarketing reports include bowel obstruction, dysphagia, esophageal obstruction, fecal impaction, hypertriglyceridemia, pancreatitis, and increased transaminases	625mg Tablet	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄy¨ Kiv †h‡Z cv‡i |	c‡qvRb †bB wea|q Av‡e`b bvgÄy¨ Kiv nj |
		r) Colesevelam HCl 3.75gm/Sachet Powder for Oral Suspension Colesevelam HCl INN 3.75gm/Sachet **Antihyperlipidemic**	Do	Do	625mg Tablet	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄy¨ Kiv †h‡Z cv‡i |	c‡qvRb †bB wea|q Av‡e`b bvgÄy¨ Kiv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg		wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Ziska Pharmaceuticals Ltd.	s)	Aspirin 25 mg + extended-release Dipyridamole 200 mg Capsule Aspirin USP 25mg + extended-release Dipyridamole USP 200mg **Platelet aggregation Inhibtor**	It is a combination is an antiplatelet agent indicated to reduce the risk of stroke in patients who have had transient ischemia of the brain or completed ischemic stroke due to thrombosis.	**Contraindications:** Hypersensitivity to any product ingredients, Patients with known allergy to NSAIDs, Patients with the syndrome of asthma, rhinitis, and nasal polyps. **Side-effects:** The most frequently reported adverse reactions (>10% and greater than placebo) were headache, dyspepsia, abdominal pain, nausea, and diarrhea.	Aspirin 75/100/150/300mg Tablet & Dipyridamole 100mg Tablet	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		t)	Olmesartan Medoxomil 40mg + Amlodipine 5 mg + Hydrochlorothiazide 25 mg Tablet Olmesartan medoxomil INN 40mg + Amlodipine Besilate BP 6.94 mg e.q. to 5 mg Amlodipine + Hydrochlorothiazide BP 25mg **Antihypertensive + Diuretic**	This is a combination of an angiotensin 2 receptor blocker, adihydropyridine calcium channel blocker, and a thiazide diuretic indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. It is not indicated for initial therapy	**Contraindications:** Anuria: Hypersensitivity to sulfonamide-derived drugs Do not co-administer aliskiren with this drug in patients with diabetes **Side-effects:** Most common adverse reactions (incidence ≥2%) are dizziness, peripheral edema, headache, fatigue, nasopharyngitis, muscle spasms, nausea, upper respiratory tract infection, diarrhea, urinary tract infection, and joint swelling**.**	Olmesartanl 40mg + Amlodipine 5mg Tablet & Hydrochlorothiazide 12.5mg + Olmesartan Medoxomil 40	USFDA	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv nj
		u)	Olmesartan Medoxomil 40mg + Amlodipine 10 mg + Hydrochlorothiazide 25 mg Tablet Olmesartan medoxomil INN 40mg + Amlodipine Besilate BP 13.87 mg e.q. to 10mg Amlodipine + Hydrochlorothiazide BP 25mg **Antihypertensive + Diuretic**	This is a combination of an angiotensin 2 receptor blocker, adihydropyridine calcium channel blocker, and a thiazide diuretic indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. • It is not indicated for initial therapy	**Contraindications:** Anuria: Hypersensitivity to sulfonamide-derived drugs Do not co-administer aliskiren with this drug in patients with diabetes. **Side-effects:** Most common adverse reactions (incidence ≥2%) are dizziness, peripheral edema, headache, fatigue, nasopharyngitis, muscle spasms, nausea, upper respiratory tract infection, diarrhea, urinary tract infection, and joint swelling	Olmesartanl 40mg + Amlodipine 5mg Tablet & Hydrochlorothiazide 12.5mg + Olmesartan Medoxomil 40	USFDA	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Ziska Pharmaceuticals Ltd.	v) Collagenase 250U/gm Ointment Collagenase USP 250U/gm	Collagenase Ointment is indicated for debriding chronic dermal ulcers and severely burned areas.	**Contraindications:** Collagenase Ointment is contraindicated in patients who have shown local or systemic hypersensitivity to collagenase. **Side-effects:** No allergic sensitivity or toxic reactions have been noted in clinical use when used as directed. However, one case of systemic manifestations of hypersensitivity to collagenase in a patient treated for more than one year with a combination of collagenase and cortisone has been reported.	New		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj	
		w) Sumatriptan 6 mg /0.5 ml Prefilled Injection Sumatriptan Succinate BP 8.4 mg e.q.to 6.0 mg Sumatriptan/0.5 ml **Antimigrane**	Sumatriptanis a serotonin (5-HT1B/1D) receptor agonist indicated for acute treatment of migraine with or without aura in adults. **Limitations of Use:** • Use only if a clear diagnosis of migraine headache has been established. • Not indicated for the prevention of migraine attacks.	**Contraindications:** Coronary artery disease or coronary artery vasospasm, Wolff-Parkinson-White syndrome or other cardiac accessory conduction pathway disorders, History of stroke, transient ischemic attack, or hemiplegic or basilar migraine, Peripheral vascular disease, Ischemic bowel disease, Uncontrolled hypertension. Recent (within 24 hours) use of another 5-HT1 agonist (e.g., another triptan) or of an ergotamine-containing medication. Concurrent or recent (past 2 weeks) use of monoamine oxidase-A inhibitor. Hypersensitivity to Sumatriptan (angioedema and anaphylaxis seen), Severe hepatic impairment **Side effects:** Most common adverse reactions (>5% and > placebo) were injection site reactions, tingling, dizziness/vertigo, warm/hot sensation, burning sensation, feeling of heaviness, pressure sensation, flushing, feeling of tightness, and numbness	50mg & 100mg Tablet	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj	

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Ziska Pharmaceuticals Ltd	x) Calcipotriene 0.005% + Betamethasone 0.064% Ointment Calcipotriene Hydrate BP 5218mcg eq.to 5000 mcg of Calcipotriene + Betamethasone Dipropionate BP 0.0643 gm eq.to 0.050gm Betamethasone/100gm **Antipsoriatic**	This Ointment is a vitamin D analogue and corticosteroid combination product indicated for the topical treatment of plaque psoriasis in patients 12 years of age and older.	**Contraindications:** None **Side-effects:** The most common adverse reactions (>1%) are pruritus and scaly rash	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
	.	y) Infliximab 100 mg/20ml vial lyophilized Injection Infliximab INN 100 mg/20ml vial **Immunomodulutor**	Infliximab is a tumor necrosis factor (TNF) blocker indicated for: **Crohn's Disease:** reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. • reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease. **Pediatric Crohn's Disease :** Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy. **Ulcerative Colitis :** •reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active disease who have had an inadequate response to	**Contraindications:** Infliximab doses >5mg/kg in moderate to severe heart failure. Previous severe hypersensitivity reaction to Infliximab or known hypersensitivity to inactive components of Infliximab or to any murine proteins. **Side-effects:** Most common adverse reactions (>10%) – infections (e.g. upper respiratory, sinusitis, and pharyngitis), infusion-related reactions, headache, and abdominal pain.	100mg/10ml Vial	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

			conventional therapy. **Pediatric Ulcerative Colitis :** •reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active disease who have had an inadequate response to conventional therapy. **Rheumatoid Arthritis:** in combination with methotrexate: •reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active disease. **Ankylosing Spondylitis** : •reducing signs and symptoms in patients with active disease. **Psoriatic Arthritis :** reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function. **Plaque Psoriasis:** Treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.					

bs	c¯ZKvi‡Ki bvg	Jl‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
08	Beximco Pharmaceuticals Limited Tongi ,Gazipur	a) Tedizolid Phosphate 200mg Tablet Tedizolid Phosphate In-house 200 mg **Antibacterial**	Tedizolid is an oxazolidinone-class antibacterial drug indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Tedizolid and other antibacterial drugs. Tedizolid should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.	**Contraindications:** None **Side Effects:** The most common adverse reactions (>2%) are nausea, headache, diarrhea, vomiting, and dizziness.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		b) Tedizolid Phosphate 200mg/Vial lyophilized powder for Injection Tedizolid Phosphate In-house 200 mg/Vial **Antibacterial**	Tedizolid is an oxazolidinone-class antibacterial drug indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Tedizolid and other antibacterial drugs. Tedizolid should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.	**Contraindications:** None **Side Effects:** The most common adverse reactions (>2%) are nausea, headache, diarrhea, vomiting, and dizziness.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		c) Phentermine 3.75mg + Topiramate 23mg Extended-Release Capsule Sustaine Released pellets of Phentermine and Topiramate Ph. Grade 133.00mg containing Phentermine USP 3.75 mg+ Topiramate USP 23mg **Anorectic Agent**	It is a combination of phentermine, a sympathomimetic amine anorectic, and topiramate , an antiepileptic drug, indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: 30 kg/m2 or greater (obese)) or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia **Limitations of Use:** The effect of the drug on cardiovascular morbidity and mortality has not been established. The safety and effectiveness of the drug in combination with other products intended for weight loss, including prescription and over-the-counter drugs, and herbal preparations, have not been established	**Contraindications:** Pregnancy Glaucoma, Hyperthyroidism ●During or within 14 days of taking monoamine oxidase inhibitors **Side effects:** Most common adverse reactions are: paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth	New	USFDA	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb †bB weavq Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
	Beximco Pharmaceuticals Limited Tongi ,Gazipur	d) Phentermine 7.5mg+ Topiramate 46mg Extended-Release capsule Sustaine Released pellets of Phentermine and Topiramate Ph. Grade 266.00mg containing Phentermine USP 7.5 mg+ Topiramate USP 46mg **Anorectic Agent**	Do	Do	Topiramate 25mg/50mg/100mg Tablet	USFDA	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb †bB weavq Av‡e`b bvgÄyi Kiv nj
		e) Decapeptide 0.100gm/100ml Lotion Decapeptide INN 0.100gm/100ml **Angioedema Suppressant**	It is used as a treatment for vitiligo. Topical application of the drug on vitiligo patches produces normal pigmentation by stimulating the multiplication of pigment producing cells, melanocytes, at the root of hair and at the edges of the vitiligo/white patch and their migration. Vitiligo is a skin disorder characterized by hypopigmentation (excessive lightening or whitening). Irregular white patches appear on the skin, giving it a clearly noticeable uneven color.	No contraindications or side effects have been reported.	New		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
	Beximco Pharmaceuticals Limited Tongi ,Gazipur	f) Sofosbuvir 400mg + Ledipasvir 90mg Tablet Sofosbuvir INN 400mg + Ledipasvir INN 90mg **Antiviral**	It is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults	**Contraindication**: None **Side-effects:** The most common adverse reactions (incidence greater than or equal to 10%, all grades) observed with treatment with this for 8, 12, or 24 weeks are fatigue and headache.	Sofosbuvir 400mg Tablet	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		g) Varenicline 1 mg Tablet Varenicline Tartrate INN 1.71mg eq. to Varenicline 1mg **Smoking Cessation Agent**	It is a nicotinic receptor partial agonist indicated for use as an aid to smoking cessation treatment	**Contraindications:** It is contraindicated in patients with a known history of serious hypersensitivity reactions or skin reactions to the molecule. **Side effects:** Most common adverse reactions were nausea, abnormal (e.g., vivid, unusual, or strange) dreams, constipation, flatulence, and vomiting.	0.50 mg Tablet	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 62 Zg mfvi wm×vš	mfvi wm×vš
09.	Sun Pharmaceutical (Bangladesh) Ltd.	a) Elemental Calcium 225.0mg + Vitamin D3 800IU Tablet Calcium Carbonate (from Coral Grains) IP 562.50mg eq. to Elemental Calcium 225 mg + Vitamin D3 IP 800 IU **Mineral + Vitamin**	• Prevention and treatment of osteoporosis. • For the treatment of hypocalcemic states dietary supplementation • Healthy bone formation and maintenance. • To reduce phosphate absorption from the gut in patients with hyperphosphatemia. • Treatment of chronic renal failure.	Hypersensitivity to any component of the product. Hypercalcaemia for example, as a result of hyperparathyroidism, vitamin D overdose, decalcifying tumours scuh as myeloma, bone metastases or sarcoidosis. Severe hypercalciuria, renal stones. Osteoporosis due to immobilization. The use of calcium supplements causes mild gastro-intestinal disturbances, such as constipation, flatulence, nausea, gastric pain, diarrhoea. Following administration of vitamin D supplements occasional skin rash has been reported. Hypercalcuria, and in rare cases hypercalcaemia have been seen with long term treatment at high dosage.	Elemental Calcium 500mg + Vitamin D3 200 IU Tablet Elemental Calcium 600mg + Vitamin D3 400 IU Tablet		Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KvgvUi 62 Zg mfvi wm×vš	mfvi wm×vš
10	General Pharmaceuticals Ltd.	a) Pentazocine 30mg/ml Injection Pentazocine Lactate BP 39.480mg eq. to 30mg Pentazocine/ml **Opioid Analgesic**	For the relief of moderate to severe pain. It may also be used for preoperative or preanesthetic medication and as a supplement to surgical anesthesia.	Contraindications: Pentazocine should not be administered to patients who are hypersensitive to it. Side effects: The most commonly occurring reactions are: nausea, dizziness or lightheadedness, vomiting, euphoria. Dermatologic Reactions: Soft tissue induration, nodules, and cutaneous depression can occur at injection sites. Ulceration (sloughing) and severe sclerosis of the skin and subcutaneous tissues (and, rarely, underlying muscle) have been reported after multiple doses. Other reported dermatologic reactions include diaphoresis, sting on injection, flushed skin including plethora, dermatitis including pruritus. Infrequently occurring reactions are—respiratory: respiratory depression, dyspnea, transient apnea in a small number of newborn infants whose mothers received Pentazocine Lactate Injection during labor; cardiovascular: circulatory depression, shock, hypertension; CNS effects: dizziness, lightheadedness, hallucinations, sedation, euphoria, headache, confusion, disorientation; infrequently weakness, disturbed dreams, insomnia, syncope, visual blurring and focusing difficulty, depression; and rarely tremor, irritability, excitement, tinnitus; gastrointestinal: constipation, dry mouth; other: urinary retention, headache, paresthesia, alterations in rate or strength of uterine contractions during labor. Rarely reported reactions include—neuromuscular and psychiatric: muscle tremor, insomnia, disorientation,.	25mg Tablet	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

2.2 Proposed Product for Locally Manufacture (Human)

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvMbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
01	Beacon Pharmaceuticals Ltd.	a) Folic Acid 5mg + Cyanocobalamin 15mcg Tablet Folic Acid BP 5mg + Cyanocobalamin BP 15mcg **Vitamin**	Folate and vitamin B12 are interrelated in function. They convert carbohydrates into energy and are vital in the metabolism of fats and protein. They play an important role in the maintenance of muscle tone in the GI tract and the integrity of skin, hair and the liver. They are also critical for maintaining red blood cell homeostasis and healthy homocysteine levels. Adequate folate status is critical for nucleic acid synthesis and neurotransmitter synthesis. At the molecular level, the main function of folate is to donate methyl groups in key biochemical reactions occurring in blood cells, neurons, the vasculature and many other tissues. In recent studies, methylcobalamin has demonstrated an enhanced ability to support neurological function. Vitamin B12 promotes protein synthesis for maintaining healthy nerve cells and myelin. Methylcobalamin may also help to moderate levels of glutamate in the brain, encouraging healthy brain cell activity, as well as memory, mood, and cognitive function. In general, vitamin B12 works with folate to promote DNA and red blood cell health.	**Contraindication**: The use of Vitamin B12 and Folic acid is contraindicated for patients with a history of Kidney Stone, Kidney Disease, Sarcoidosis, High Amount of Phosphate in the Blood, High Amount of Calcium in the Blood, Low Amount of Potassium in the Blood, Excessive Amount of Vitamin D in the Body. **Side-effect:** Rarely gastro-Intestinal disturbances.	New		c‡qvRb †bB wea|q Av‡e`b bvgÄyK iv ‡h‡Z cv‡i |	c‡qvRb †bB wea|q Av‡e`b bvgÄyK iv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Beacon Pharmaceuticals Ltd.	b) Rasagiline Mesilate 1mg Tablet Rasagiline Mesilate INN 1.516mg eq. to 1mg Rasagiline **Antiparkinsonian**	It a monoamine oxidase (MAO)-B inhibitor (MAOI), is indicated for the treatment of Parkinson's disease	**Contraindications:** Concomitant use of meperidine, tramadol, methadone, propoxyphene dextromethorphan, St. John's wort, cyclobenzaprine, or another (selective or non-selective) MAO inhibitor **Side-effect:** Most common adverse reactions (incidence 3% or greater than placebo): Rasagiline Mesilate Monotherapy: flu syndrome, arthralgia, depression, dyspepsia Rasagiline Mesilate used as adjunct without levodopa: peripheral edema, fall, arthralgia, cough, and insomnia Rasagiline Mesilate used as adjunct to levodopa: dyskinesia, accidental injury, weight loss, postural hypotension, vomiting, anorexia, arthralgia, abdominal pain, nausea, constipation, dry mouth, rash, abnormal dreams, fall, and tenosynovitis	New	USFDA	Abyjgvw`b Kiv †h‡Z cv‡i	Abyjgvw`b Kiv nj
		c) Remifentanil 1mg/Vial Injection Remifentanil HCl INN 1.097mg eq. to 1mg Remifentanil **Analgesic**	Remifentanil is indicated for IV administration: 1. As an analgesic agent for use during the induction and aintenance of general anesthesia for inpatient and outpatient procedures. 2. For continuation as an analgesic into the immediate postoperative period in adult patients under the direct supervision of an anesthesia practitioner in a postoperative anesthesia care unit or intensive care setting. 3. As an analgesic component of monitored anesthesia care in adult patients	**Contraindication**: - As glycine is present in the formulation Remifentanil for injection is contra-indicated for epidural and intrathecal use. - Remifentanil is contra-indicated in patients with known hypersensitivity to any component of the preparation and other fentanyl analogues **Side-effect:** Remefentanil produces adverse events that are characteristic of μ-opioids, such as respiratory depression, bradycardia, hypotension, and skeletal muscle rigidity. These adverse events dissipate within minutes of discontinuing or decreasing the infusion rate of Remifentanil.	New	USFDA BNF-69 Page No-884	Abyjgvw`b Kiv †h‡Z cv‡i	Abyjgvw`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Beacon Pharmaceuticals Ltd.	d) Zonisamide 50mg Hard Gelatin Capsule Zonisamide USP 50mg **Anticonvulsant**	Zonisamide capsules are indicated as adjunctive therapy in the treatment of partial seizures in adults with epilepsy.	**Contraindication**: Zonisamide is contraindicated in patients who have demonstrated hypersensitivity to sulfonamides or zonisamide. **Side-effect:** The most commonly observed adverse events related to treatment with Zonisamide (an incidence at least 4% greater than placebo) in controlled clinical trials and shown in descending order of frequency were somnolence, anorexia, dizziness, ataxia, agitation/irritability, and difficulty with memory and/or concentration.	New	USFDA BNF-69 Page No-321	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		e) Zonisamide 100mg Hard Gelatin Capsule Zonisamide USP 100mg **Anticonvulsant**	Do	Do	New	USFDA BNF-69 Page No-321	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		f) Zinc Orotate 60mg Film Coated Tablet Zinc Orotate INN 60mg **Mineral**	Zinc deficiency, Diarrhea, An inherited disorder called Wilson's disease.	**Contraindication**: Large doses of zinc can lower blood sugar in people with diabetes. High doses above the recommended amounts might cause fever, coughing, stomach pain, fatigue. **Side-effect:** Side-effects include constipation, dry mouth, nausea, vomiting, tachycardia, dizziness, confusion, euphoria, hallucinations, impaired memory, anxiety, restlessness, urinary retention, blurred vision, and rash. Angle-closure glaucoma may occur very rarely.	Zinc 10mg Tablet		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		g) Tetrabenazine INN 25mg Tablet Tetrabenazine INN 25mg **CNS Agent**	Tetrabenazine is indicated for the treatment of chorea associated with Huntington's disease.	**Contraindication**: Depression, Parkinsonism, Phaeochromocytoma, Prolactin-dependent tomours **Side-effect:** The following risks are discussed in greater detail in other sections of the labeling: Depression and suicidality, Akathisia, restlessness and agitation, Parkinsonism, Sedation and somnolence Dysphagia	New	BNF-69 Page No-337	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Beacon Pharmaceuticals Ltd.	h) Tetrabenazine INN 12.5mg Tablet Tetrabenazine INN **CNS Agent**	Tetrabenazine is indicated for the treatment of chorea associated with Huntington's disease.	**Contraindication**: Depression, Parkinsonism, Phaeochromocytoma, Prolactin-dependent tomours **Side-effect:** The following risks are discussed in greater detail in other sections of the labeling: Depression and suicidality, Akathisia, restlessness and agitation, Parkinsonism, Sedation and somnolence Dysphagia	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		i) Glatiramer Acetate 20mg/ml Injection Glatiramer Acetate INN 20mg/ml **Multiple sclerosis Agent**	It is indicated for the treatment of patients with relapsing forms of multiple sclerosis.	**Contraindication**: It is contraindicated in patients with known hypersensitivity to glatiramer acetate or mannitol. **Side-effect:** In controlled studies of Glatiramer Acetate 20 mg/mL, most common adverse reactions (≥10% and ≥1.5 times higher than placebo) were: injection site reactions, vasodilatation, rash, dyspnea and chest pain. In a controlled study of Glatiramer Acetate 40 mg/mL, most common adverse reactions (≥10% and ≥1.5 times higher than placebo) were: injection site reactions.	New	BNF-69 Page No-664	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		l) Regorafenib 40mg Film Coated Tablet Regorafenib INN 40mg **Anticancer**	Regorafenib is a kinase inhibitor indicated for the treatment of patients with: • Metastatic colorectal cancer (CRC) who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan- based chemotherapy, an antiVEGF therapy, and,if KRAS wild type, an anti-EGFR therapy. • Locally advanced, unresectable or metastatic gastrointestinal stromal tumor (GIST) who have been previously treated with imatinib mesylate and Sunitinib malate.	**Contraindication**: None **Side-effect:** The most common adverse reactions (≥20%) are asthenia/fatigue, HFSR, diarrhea, decreased appetite/food intake, hypertension, mucositis, dysphonia, infection, pain (not otherwise specified), decreased weight, gastrointestinal and abdominal pain, rash, fever, and nausea.	New	USFDA BNF-69 Page No-618	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †Rvbv‡iK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-Kvgv‡Ui 63 Zg mfvi wm×vš	mfvi wm×vš
	Beacon Pharmaceuticals Ltd.	m) Nivolumab 100 mg/10ml Injection Nivolumab INN 100 mg/10ml **Anticancer**	Nivolumab is a programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of patients with: Unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. This indication is approved under accelerated approval based on tumor Response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. Metastatic squamous non-small cell lung cancer with progression on or after platinum-based chemotherapy.	**Contraindication**: None. **Side-effect:** Most common adverse reaction (>20%) in patients with melanoma was rash. Most common adverse reactions (>20%) in patients with advanced squamous non-small cell lung cancer were fatigue, dyspnea, musculoskeletal pain, decreased appetite, cough, nausea, and constipation.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |
		n) Nivolumab 40mg/4ml Injection Nivolumab INN 40mg/4ml **Anticancer**	Do	Do	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |
		o) Apremilast 10mg Film Coated Tablet Apremilast INN 10mg **Antiinflammatory**	It is an inhibitor of phosphodieasterase 4 (PDE4), is indicated for the treatment of adult patients with active psoriatic arthritis	**Contraindication**: Contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation **Side-effect:** The most common adverse reactions are diarrhea, nausea and headache.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |
		p) Ezogabine INN 50mg Film Coated Tablet Ezogabine INN 50mg **Anticonvulsant**	It is a potassium channel opener indicated as adjunctive treatment of partial-onset seizures in patients aged 18 years and older who have responded inadequately to several alternative treatments and for whom the benefits outweigh the risk of retinal abnormalities and potential decline in visual acuity.	**Contraindications: None** **Side-effect:** The most common adverse reactions (incidence > 4% and approximately twice placebo) are dizziness, somnolence, fatigue, confusional state, vertigo, tremor, abnormal coordination, diplopia, disturbance in attention, memory impairment, asthenia, blurred vision, gait disturbance, aphasia, dysarthria, and balance disorder.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Beacon Pharmaceuticals Ltd.	q) Sofosbuvir 400mg + Ledipasvir 90mg Film Coated Tablet Sofosbuvir INN 400mg + Ledipasvir INN 90mg **Antiviral**	Ledipasvir & Sofosbuvir Tablet is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults.	**Contraindications:** None known. **Side Effects:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The safety assessment of Ledipasvir & Sofosbuvir was based on pooled data from three Phase 3 clinical trials of subjects with genotype 1 chronic hepatitis C (CHC) with compensated liver disease (with and without cirrhosis) including 215, 539, and 326 subjects who received Ledipasvir & Sofosbuvir for 8, 12 and 24 weeks, respectively The proportion of subjects who permanently discontinued treatment due to adverse events was 0%, <1%, and 1% for subjects receiving Ledipasvir & Sofosbuvir for 8, 12, and 24 weeks, respectively. The most common adverse reactions (≥10%) were fatigue and headache in subjects treated with 8, 12, or 24 weeks of Ledipasvir & Sofosbuvir. <u>Laboratory Abnormalities</u> *Bilirubin Elevations:* Bilirubin elevations of greater than 1.5xULN were observed in 3%, <1% and 2% of subjects treated with ledipasvir & sofosbuvir for 8, 12, and 24 weeks, respectively. *Lipase Elevations:* Transient, asymptomatic lipase elevations of greater than 3xULN were observed in <1%, 2%, and 3% of subjects treated with Ledipasvir & Sofosbuvir for 8, 12, and 24 weeks, respectively. *Creatine Kinase:* Creatine kinase was not assessed in Phase 3 trials Ledipasvir & Sofosbuvir. Isolated, asymptomatic creatine kinase elevations (Grade 3 or 4) have been previously reported in subjects treated with sofosbuvir in combination with ribavirin or peginterferon/ribavirin in other clinical trials.	Sofosbuvir 400mg Tablet	USFDA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj

bs	c¯ZKvi‡Ki bvg		JI‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Beacon Pharmaceuticals Ltd.	r)	Doxepin 3 mg Tablet Doxepin Hydrochloride USP 3.392mg eq. To Doxepin 3mg **Antidepressants**	Doxepin tablets are indicated for the treatment of insomnia characterized by difficulties with sleep maintenance.	**Contraindication**: Hypersensitivity to doxepin hydrochloride, inactive ingredients, or other dibenoxepines. Co-administration with Monoamine Oxidase Inhibitors (MAOIs): Do not administer if patient is taking MAOIs or has used MAOIs within the past two weeks. Untreated narrow angle glaucoma or severe urinary retention **Side-effect:** The most common treatment-emergent adverse reactions, reported in ≥ 2% of patients treated with Silenor, and more commonly than in patients treated with placebo, were somnolence/sedation, nausea, and upper respiratory tract infection.	75mg Capsule 5gm/100 gm Cream	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		s)	Doxepin 6 mg Tablet Doxepin Hydrochloride USP 6.783 mg eq. To Doxepin 6mg **Antidepressants**	Do	Do	75mg Capsule 5gm/100gm Cream	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		t)	Trazodone HCl 150mg ER Tablet Trazodone HCl USP 150mg **Antidepressants**	It is indicated for the treatment of major depressive disorder. Efficacy was established in one 8-week trial of Trazodone HCl 150mg ER Tablet as well as in trials of trazodone immediate release formulation in patients with major depressive disorder.	**Contraindication**: None **Side-effect:** Most common adverse reactions (incidence ≥5% and twice that of placebo) are: somnolence/sedation, dizziness, constipation, vision blurred	New	USFDA (Discontinue)	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj
		u)	Isocarboxazid 10mg Talet Isocarboxazid INN 10mg **Antidepressants**	It is indicated for the treatment of depression. Because of its potentially serious side effects, Isocarboxazid is not an antidepressant of first choice in the treatment of newly diagnosed depressed patients. The efficacy of Isocarboxazid in the treatment of depression was established in 6-week controlled trials of depressed outpatients. These patients had symptoms that corresponded to the DSM-IV category of major depressive disorder; however, they often also	**Contraindication**: Isocarboxazid should not be administered in combination with any of the following: MAO inhibitors or dibenzazepine derivatives; sympathomimetics (including amphetamines); some central nervous system depressants (including narcotics and alcohol); antihypertensive, diuretic, antihistaminic, sedative or anesthetic drugs, buproprion HCL, buspirone HCL, dextromethorphan, cheese or other foods with a high tyramine content; or excessive quantities of caffeine. Isocarboxazid (isocarboxazid) should not be administered to any patient with a confirmed or suspected cerebrovascular defect or to any patient with cardiovascular disease, hypertension, or history	New	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj

			had signs and symptoms of anxiety (anxious mood, panic, and/or phobic symptoms). (See Clinical Pharmacology) A major depressive episode (DSM-IV) implies a prominent and relatively persistent (nearly every day for at least 2 weeks) depressed or dysphoric mood that usually interferes with daily functioning, and includes at least five of the following nine symptoms: depressed mood, loss of interest in usual activities, significant change in weight and/or appetite, insomnia or hypersomnia, psychomotor agitation or retardation, increased fatigue, feelings of guilt or worthlessness, slowed thinking or impaired concentration, and a suicide attempt or suicidal ideation. The antidepressant effectiveness of Isocarboxazid in hospitalized depressed patients, or in endogenomorphically retarded and delusionally depressed patients, has not been adequately studied. The effectiveness of Marplan in long-term use, that is, for more than 6 weeks, has not been systematically evaluated in controlled trials. Therefore, the physician who elects to use Marplan for extended periods should periodically evaluate the long-term usefulness of the drug for the individual patient.	of headache. **Contraindicated Patient Populations** Hypersensitivity Isocarboxazid should not be used in patients with known hypersensitivity to isocarboxazid. Cerebrovascular Disorders Isocarboxazid should not be administered to any patient with a confirmed or suspected cerebrovascular defect or to any patient with cardiovascular disease or hypertension. Pheochromocytoma Marplan should not be used in the presence of pheochromocytoma, as such tumors secrete pressor substances whose metabolism may be inhibited by Isocarboxazid. Liver Disease Isocarboxazid should not be used in patients with a history of liver disease, or in those with abnormal liver function tests. Renal Impairment Isocarboxazid should not be used in patients with severe impairment of renal function. Patients with Severe/Frequent Headaches Patients with severe or frequent headaches should not be considered candidates for therapy with Isocarboxazid, because headaches during therapy may be the first symptom of a hypertensive reaction to the drug. **Side-effect:** Adverse Findings Observed in Short-Term, Placebo-Controlled Trials Systematically collected data are available from only 86 patients exposed to Isocarboxazid, of whom only 52 received doses of $50 mg/day, including only 11 who were dosed at $60 mg/day. Because of the limited experience with systematically monitored patients receiving Isocarboxazid at the higher end of the currently recommended dose range of up to 60 mg/day, caution is indicated in patients for whom a dose of 40 mg/day is exceeded (see WARNINGS). The table that follows enumerates the incidence, rounded to the nearest percent, of treatment emergent adverse events that occurred among 86 depressed patients who received Isocarboxazid at doses ranging from 20 to 80 mg/day in placebo-controlled trials of 6 weeks in duration. Events included are those occurring in 1% or more of patients treated with Isocarboxazid and for which the incidence in patients treated with Isocarboxazid was greater than the incidence in placebo-treated patients. The prescriber should be aware that these figures cannot be used to predict the incidence of adverse events in the course of usual medical practice where patient characteristics and other factors differ				

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Beacon Pharmaceuticals Ltd.	v) Deflazacort 1mg Tablet Deflazacort INN 1.0mg **Glucocorticoid**	Rheumatoid arthritis, juvenile chronic arthritis, asthma and other airway diseases, pemphigus, uveitis, nephrotic syndrome,Immune suppression in transplantation, anaphylaxis, severe hypersensitivity reactions, dermatomyositis, mixed connective tissue disease, polyarteritis nodosa, bullous pemphigoid, ulcerative colitis, optic neuritis, autoimmune haemolytic anaemia, idiopathic thrombocytopenic purpura, acute and lymphatic leukaemia, malignant lymphoma.	**Contraindication**: Systemic infection unless specific anti-infective therapy is employed. Hypersensitivity to Deflazacort or any of the ingredients. Patients receiving live virus immunization. **Side-effect:** Deflazacort is associated with side effects like skin lesions such as acne, bruises or stretch marks, recurrent infections, stomach upset, muscle or bone weakness, Cushing's syndrome, menstrual cycle irregularities or hirsutism.	6mg Tab.		c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj |
		w) Deflazacort 24mg Tablet Deflazacort INN 24mg **Glucocorticoid**	Do	Do	6mg Tab		c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj |
		x) Deflazacort 30mg Tablet Deflazacort INN 30mg **Glucocorticoid**	Do	Do	6mg Tab.		c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj |
		y) Darbepoietin Alfa 40mcg/0.4ml Prefilled syringe Injection Darbepoietin Alfa INN 40mcg/0.4ml **Hematopoietic**	Darbepoietin Alfa is an erythropoiesis-stimulating agent (ESA) indicated for the treatment of anemia due to: • Chronic Kidney Disease (CKD) in patients on dialysis and patients not on dialysis • The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy **Limitations of Use:** Darbepoietin Alfa has not been shown to improve quality of life, fatigue, or patient well-being. Darbepoietin Alfa is not indicated for use: • In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy • In patients with cancer receiving myelosuppressive chemotherapy when the anticipated outcome is cure	**Contraindication**: •Uncontrolled hypertension • Pure red cell aplasia (PRCA) that begins after treatment with Darbepoietin Alfa or other erythropoietin protein drugs • Serious allergic reactions to Darbepoietin Alfa . **Side-effect:** Patients with CKD: Adverse reactions in ≥ 10% of Darbepoietin Alfa -treated patients in clinical studies were hypertension, dyspnea, peripheral edema, cough, and procedural hypotension • 1% of≥Cancer Patients Receiving Chemotherapy: Adverse reactions in Darbepoietin Alfa -treated patients in clinical studies were abdominal pain, edema, and thrombovascular events	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Beacon Pharmaceuticals Ltd.	z) Daclatasvir 60mg film coated Tablet Daclatasvir Dihydrochloride INN eq. To Daclatasvir 60mg **Antiviral**	Daclatasvir is indicated in Combination with other medicinal products for the treatment of Chronic hepatitis C virus (HCV) infection in adults.	**Contraindication**: Hypersensitivity to the active substance or to any of the excipients. Coadministration with medical products that strongly induce cytochrome p450 3A4 (CYp3A4) and P-glycoprotein transporter and thus may be lead to lower exposure and loss of efficacy of Daclatasvir. This active substance include but are not limited to phenytoin, carbanazepine , rifampicin, systemic dexamethasone and the herbal product St. John's wort. **Side-effect:**Nausea, vomiting, tachycardia, Hypotension, headache, hot flushes, rash, fever,insomnia	New	EMA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		aa) Aripiprazole 9.75mg/1.3ml Injection Aripiprazole USP 9.75mg/1.3ml **Antipsychotic**	It is an atypical antipsychotic indicated as the injection is indicated for Agitation associated with schizophrenia or bipolar mania.	**Contraindications:** Known hypersensitivity to Aripiprazole. **Side effects:** Adult patients with schizophrenia: akathisia • Pediatric patients (13 to 17 years) with schizophrenia: extrapyramidal disorder, somnolence, and tremor • Adult patients (monotherapy) with bipolar mania: akathisia, sedation, restlessness, tremor, and extrapyramidal disorder • Adult patients (adjunctive therapy with lithium or valproate) with bipolar mania: akathisia, insomnia, and extrapyramidal disorder • Pediatric patients (10 to 17 years) with bipolar mania: somnolence, extrapyramidal disorder, fatigue, nausea, akathisia, blurred vision, salivary hypersecretion, and dizziness • Adult patients with major depressive disorder (adjunctive treatment to antidepressant therapy): akathisia, restlessness, insomnia, constipation, fatigue, and blurred vision • Pediatric patients (6 to 17 years) with autistic disorder: sedation, fatigue, vomiting, somnolence, tremor, pyrexia, drooling, decreased appetite, salivary hypersecretion, extrapyramidal disorder, and lethargy • Adult patients with agitation associated with schizophrenia or bipolar mania: nausea.	5mg, 10mg, 15mg Tablet	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvMvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Beacon Pharmaceuticals Ltd.	ab) Suvorexant 5mg Tablet Suvorexant INN 5mg **Orexin Receptor antagonist**	It is an orexin receptor antagonist indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance	**Contraindication**: Do not use in patients with narcolepsy **Side-effect:** The most common adverse reaction (reported in 5% or more of patients treated with Suvorexant and at least twice the placebo rate) with Suvorexant was somnolence	New	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj |
		Ac) Fludrocortisone Acetate 0.100mg Tablet Fludrocortisone Acetate BP 0.100mg **Steroid**	Fludrocortisone Acetate is indicated as partial replacement therapy for primary and secondary adrenocortical insufficiency in Addison's disease and for the treatment of salt-losing adrenogenital syndrome.	**Contraindications:** Corticosteroids are contraindicated in patients with systemic fungal infections and in those with a history of possible or known hypersensitivity to these agents. **Side Effects:** Most adverse reactions are caused by the drug's mineralocorticoid activity (retention of sodium and water) and include hypertension, edema, cardiac enlargement, congestive heart failure, potassium loss, and hypokalemic alkalosis. When fludrocortisone is used in the small dosages recommended, the glucocorticoid side effects often seen with cortisone and its derivatives are not usually a problem; however the following untoward effects should be kept in mind, particularly when fludrocortisone is used over a prolonged period of time or in conjunction with cortisone or a similar glucocorticoid. Musculoskeletal-muscle weakness, steroid myopathy, loss of muscle mass, osteoporosis, vertebral compression fractures, aseptic necrosis of femoral and humeral heads, pathologic fracture of long bones, and spontaneous fractures. Gastrointestinal-peptic ulcer with possible perforation and hemorrhage, pancreatitis, abdominal distention, and ulcerative esophagitis. Dermatologic-impaired wound healing, thin fragile skin, bruising, petechiae and ecchymoses, facial erythema, increased sweating, subcutaneous fat atrophy, purpura, striae, hyperpigmentation of the skin and nails, hirsutism, acneiform eruptions, and hives; reactions to skin tests may be suppressed.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |

				Neurological-convulsions, increased intracranial pressure with papilledema (pseudotumor erebri) usually after treatment, vertigo, headache, and severe mental disturbances. Endocrine-menstrual irregularities; development of the cushingoid state; suppression of growth in children; secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress (e.g., trauma, surgery, or illness); decreased carbohydrate tolerance; manifestations of latent diabetes mellitus; and increased requirements for insulin or oral hypoglycemic agents in diabetics. Ophthalmic-posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and exophthalmos. Metabolic-hyperglycemia, glycosuria, and negative nitrogen balance due to protein catabolism. Allergic Reactions-allergic skin rash, maculopapular rash, and urticaria. Other adverse reactions that may occur following the administration of a corticosteroid are necrotizing angiitis, thrombophlebitis, aggravation or masking of infections, insomnia, syncopal episodes, and anaphylactoid reactions.				

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Beacon Pharmaceuticals Ltd.	Ad) Triamcinolone Hexacetonide 5mg/ml vial Injection Triamcinolone Hexacetonide USP 5mg/ml vial **Adrenglucocorticoid**	The intralesional administration of triamcinolone hexacetonide injectable suspension,5 mg/mL is indicated for alopecia areata; discoid lupus erythematosus; keloids; localized hypertrophic, infiltrated, inflammatory lesions of granuloma annulare, lichen planus, lichen simplex chronicus (neurodermatitis), and psoriatic plaques; necrobiosis lipoidica diabeticorum. Aristospan may also be useful in cystic tumors of an aponeurosis or tendon (ganglia).	**Contraindications:** Triamcinolone Hexacetonide is contraindicated in patients who are hypersensitive to any components of this product. Intramuscular corticosteroid preparations are contraindicated for idiopathic thrombocytopenic purpura. **Side-effects:** **Allergic Reaction:** Anaphylactoid reactions, anaphylaxis, angioedema. **Cardiovascular:** Bradycardia, cardiac arrest, cardiac arrhythmias, cardiac enlargement, circulatory collapse, congestive heart failure, fat embolism, hypertension,hypertrophic cardiomyopathy in premature infants, myocardial rupture following recent myocardial infarction pulmonary edema, syncope,tachycardia, thromboembolism, thrombophlebitis, vasculitis. **Dermatologic:** Acne, allergic dermatitis, cutaneous and subcutaneous atrophy, dry scaly skin, ecchymoses and petechiae, edema, erythema, hyperpigmentation, hypopigmentation, impaired wound healing, increased sweating, rash, sterile abscess, striae, suppressed reactions to skin tests, thin fragile skin, thinning scalp hair, urticaria. **Endocrine:** Decreased carbohydrate and glucose tolerance, development of cushingoid state, glycosuria, hirsutism, hypertrichosis, increased requirements for insulin or oral hypoglycemic agents in diabetics, manifestations of latent diabetes mellitus, menstrual irregularities, secondary adrenocortical and pituitary unresponsiveness (particularly in times of stress, as in trauma, surgery, or illness), suppression of growth in pediatric patients. **Fluid and Electrolyte Disturbance:** Congestive heart failure in susceptible patients, fluid retention, hypokalemic alkalosis, potassium loss, sodium retention. **Gastrointestinal:** Abdominal distention,	Triamcinolone Acetonide 40 mg/ml Injection	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

				bowel/bladder dysfunction (after intrathecal administration), elevation in serum liver enzyme levels (usually reversible upon discontinuation), hepatomegaly, increased appetite, nausea, pancreatitis, peptic ulcer with possible perforation and hemorrhage, perforation of the small and large intestine (particularly in patients with inflammatory bowel disease), ulcerative esophagitis. **Metabolic:** Negative nitrogen balance due to protein catabolism. **Muskoskelatal:** Aseptic necrosis of femoral and humeral heads, calcinosis (following intra-articular or intralesional use), Charcot-like arthropathy, loss of muscle mass, muscle weakness, osteoporosis, pathologic fracture of long bones, postinjection flare (following intra-articular use), steroid myopathy, tendon rupture, vertebral compression fractures.				
02.	**UniMed & UniHealth Manufacturers Ltd.** Gazipur, Bangladesh	a) Trospium Chloride 60mg Prolonged Release Capsule Trospium Chloride Prolonged Release pellets Ph. Grade 250mg containing Trospium Chloride USP 60mg **Renal and Genitourinary agent, Antispasmodic**	Urinary frequency, urgency and incontinence	**Contraindications:** Antimuscarinic drugs should be avoided in patients with myasthenia gravis, significant bladder outflow obstruction or urinary retention, severe ulcerative colitis, toxic megacolon, and in gastro-intestinal obstruction or intestinal atony. **Side-effects** Side-effects of antimuscarinic drugs include dry mouth, gastro-intestinal disturbances including constipation, flatulence, taste disturbances, blurred vision, dry eyes, drowsiness, dizziness, fatigue, difficulty in micturition (less commonly urinary retention), palpitation, and skin reactions (including dry skin, rash, and photosensitivity); also headache, diarrhoea, angioedema, arrhythmias, and tachycardia. Central nervous System stimulation, such as restlessness, disorientation, hallucination, and convulsion may occur; children are at higher risk of these effects. Antimuscarinic drugs can reduce sweating, leading to heat sensations and fainting in hot environments or in patients with fever, and very rarely may precipitate angle-closure glaucoma.	New	BNF-69 Page-566	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	UniMed & UniHealth Manufacturers Ltd. Gazipur, Bangladesh	b) Trospium Chloride 20mg Tablet Trospium Chloride USP 20mg **Renal and Genitourinary agent, Antispasmodic**	Urinary frequency, urgency and incontinence	Do	New	BNF-69 Page-566	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj	
		c) Sucralfate 20gm/100ml Suspension Sucralfate BP 20gm/100ml **Antiulcerant**	It is indicated in adults and adolescents over 14 years old for treatment of duodenal ulcer, gastric ulcer, chronic gastritis, and the prophylaxis of gastrointestinal haemorrhage from stress ulceration in seriously ill patients.	**Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Side-effects**: Constipation; less frequently diarrhoea, nausea, indigestion, flatulence, gastric discomfort, back pain, dizziness, headache, drowsiness, bezoar formation, dry mouth and rash	500mg & 1000mg Tablet	BNF-69 Page-54	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj	
		d) Aspirin 100mg + Glycine 45mg Tablet Aspirin USP 100mg + Glycine USP 45mg **Platelet Aggregation inhibitor**	Prophylaxis against strokes and heart attacks. As a platelet aggregation inhibitor in patients following aortocoronary by-pass surgery, to prevent graft occlusion.	**Contraindications:** Hypersensitivity to aspirin or any other nonsteroidal anti-inflammatory drugs (NSAIDs), glycine or to any of the excipients of Cardiprin 100. Haemophilia, other coagulopathies including hypoprothrombinaemia or concurrent anticoagulant therapy. Gout. Discontinue taking any form of aspirin 1 week before surgery. History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy; active or history of recurrent peptic ulcer/haemorrhage. **Adverse Reactions:** *Blood and Lymphatic System Disorder:* Aspirin prolongs bleeding time, decreases platelet adhesiveness and, in large doses, may cause hypothrombinaemia. Thrombocytopenia may also occur. Bleeding disorders eg, epistaxis, haematuria, purpura, haemoptysis, gastrointestinal bleeding, haematoma and cerebral haemorrhage have occasionally reported. *Immune System Disorder:* Hypersensitivity reactions include skin rashes, urticaria, angioedema, asthma, headache, bronchospasm, rhinitis and rarely, anaphylaxis. *Ear and Labyrinth Disorder:* Tinnitus. *Gastrointestinal Disorders:* Gastrointestinal irritation is common in patients taking aspirin preparations, and nausea, vomiting, dyspepsia, gastritis, gastrointestinal erosions and ulceration have been reported. Anaemia may occur following chronic gastrointestinal blood loss or acute haemorrhage. *Skin and Subcutaneous*	Aspirin 75mg, 100 mg, 150 mg & 300 mg Tablet		c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	UniMed & UniHealth Manufacturers Ltd. Gazipur, Bangladesh	e) Methylphenidate Hydrochloride 27mg Prolonged-Release Tablet Methylphenidate Hydrochloride BP 27mg **CNS Stimulant**	Attention deficit hyperactivity disorder (under specialist supervision); narcolepsy [unlicensed indication]	**Contraindications:** Severe depression, suicidal ideation; anorexia nervosa; psychosis; uncontrolled bipolar disorder; hyperthyroidism; cardiovascular disease (including heart failure, cardiomyopathy, severe hypertension and arrhythmias), structural cardiac abnormalities; phaeochromocytoma; vasculitis; cerebrovascular disorders **Side-effects :** Abdominal pain, nausea, vomiting, diarrhoea, dyspepsia, dry mouth, anorexia, reduced weight gain; tachycardia, palpitation, arrhythmias, changes in blood pressure; cough, nasopharyngitis; tics (very rarely Tourette syndrome), insomnia, nervousness, asthenia, depression, irritability, aggression, headache, drowsiness, dizziness, movement disorders; fever; arthralgia; rash, pruritus, alopecia; growth restriction; less commonly constipation, dyspnoea, abnormal dreams, confusion, suicidal ideation, urinary frequency, haematuria, muscle cramps, epistaxis; rarely angina, sweating, and visual disturbances; very rarely hepatic dysfunction, myocardial infarction, cerebral arteritis, psychosis, seizures, neuroleptic malignant syndrome, tolerance and dependence, blood disorders including leucopenia and thrombocytopenia, angle-closure glaucoma, exfoliative dermatitis, and erythema multiforme; supraventricular tachycardia, bradycardia, and convulsions also reported.	5mg &10mg Tablet	BNF-69 Page-268	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
		f) Methylphenidate Hydrochloride 18mg Prolonged-Release Tablet Methylphenidate Hydrochloride BP 18mg **CNS Stimulant**	Attention deficit hyperactivity disorder (under specialist supervision); narcolepsy [unlicensed indication]	Do	5mg & 10mg Tablet	BNF-69 Page-268	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	UniMed & UniHealth Manufacturers Ltd. Gazipur, Bangladesh	g) Glutaraldehyde 2.4% Solution Strong Glutaraldehyde Solution 50% BP 4.80gm eq. to 2.40 Glutaraldehyde/100ml **Disinfectant**	Glutaraldehyde 2.4% solution is indicated for use as a sterilant when used or reused, according to directions for use, for up to a maximum of 14 days at 25°c with an immersion time of at least 10 hours.	**Contraindications** Glutaraldehyde 2.4% solution should not be used to sterilize reusable medical devices that are compatible with other available methods of sterilization that can be biologically monitored, e.g.: heat, ethylene oxide, or hydrogen peroxide gas plasma. Glutaraldehyde 2.4% solution should not be used for sterilization of critical devices intended for single use (e.g.: catheters, cannula used for intraocular lens replacement and other types of single use devices). **Adverse Reaction:** Use only in well-ventilated areas (refer to the material safety data sheets for additional information). Avoid release to the environment. 1. Direct contact is corrosive to exposed tissue, causing eye damage and skin irritation/damage. Do not get into eyes, on skin or on clothing. 2. Avoid contamination of food. 3. Refer to material safety data sheet (msds) for the following.	New		Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
	UniMed & UniHealth Manufacturers Ltd. Gazipur, Bangladesh	h) Chlorhexidine 4% Gel Chlorhexidine Digluconate Solution (20%) BP 35.50gm eq. to 7.10gm Chlorhexidine Digluconate/100gm **Antiseptic**	Chlorhexidine Digluconate 7.1% w/v gel (CHX) is a broad spectrum antiseptic that is safe and effective for reducing bacterial colonization on the skin and umbilical stump of newborns. It should be used immediately after cord cutting in the umbilical stump and surrounding area. Single application of all content of the tube is sufficient. Application of Chlorhexidine gel helps prevent bacterial infection for a long period of time	**Contraindications:** Patients who have previously experienced a hypersensitivity to chlorhexidine (such reactions are extremely rare). **Adverse Reaction:** Skin irritation may occasionally occur. Generalized allergic reactions to chlorhexidine have been reported, but are extremely rare.	1%, 2.5% and 4% Solution 1% Cream and Gel 0.5% Hand Rub		Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	UniMed & UniHealth Manufacturers Ltd. Gazipur, Bangladesh	j) Flecainide Acetate 100mg Tablet Flecainide Acetate USP 100mg **Antiarrhythmic**	Reciprocating tachycardia, arrhythmias associated with accessory conducting pathways (e.g. Wolff-Parkinson-White syndrome), disabling symptoms of paroxysmal atrial fibrillation in patients without left ventricular dysfunction (arrhythmias of recent onset will respond more readily) Immediate-release tablets only: symptomatic sustained ventricular tachycardia, disabling symptoms of premature ventricular contractions or non-sustained ventricular tachycardia in patients resistant to or intolerant of other therapy Injection only: ventricular tachyarrhythmias resistant to other treatment.	**Contra-indications** : Uncontrolled congestive heart failure with left ventricular ejection fraction less than 35%, cardiogenic shock (except arrhythmia induced), myocardial infarction within last 3 months, severe bradycardia, Brugada syndrome, electrolyte disturbances, severe obstructive pulmonary disease, marked hypotension; myasthenia gravis; unless adequately paced avoid in sinus node dysfunction, atrial conduction defects, second degree or greater AV block, bundle branch block or distal block **Side-effects** : Abdominal pain, nausea, vomiting, diarrhoea, constipation, dry mouth, taste disturbance, sino-atrial, atrioventricular, or intraventricular blocks, bradycardia, tachycardia, palpitation, chest pain, dyspnoea, dizziness, malaise, anxiety, sleep disorders, headache, blurred vision; less commonly abdominal distension, flatulence, anorexia, pro-arrhythmic effects, hypotension, syncope, ataxia, paraesthesia, erectile dysfunction, thrombocytopenia, vertigo, rash; also reported jaundice, cholestasis, hepatitis, convulsions, confusion, restlessness, extrapyramidal symptoms, reduced sperm count (reversible on withdrawal), agranulocytosis, leucopenia, granulocytopenia, lupus erythematosus-like syndrome	New	BNF-69 Page-99	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	UniMed & UniHealth Manufacturers Ltd. Gazipur, Bangladesh	k) Dofetilide 125mcg Capsule Dofetilide USP 0.125mg **Antiarrhythmic**	Dofetilide is indicated for the maintenance of normal sinus rhythm (delay in time to recurrence of atrial fibrillation/atrial flutter [AF/Afl]) in patients with atrial fibrillation/atrial flutter of greater than one week duration who have been converted to normal sinus rhythm. Because Dofetilide can cause life threatening ventricular arrhythmias, it should be reserved for patients in whom atrial fibrillation/atrial flutter is highly symptomatic. In general, antiarrhythmic therapy for atrial fibrillation/atrial flutter aims to prolong the time in normal sinus rhythm. Recurrence is expected in some patient. **Conversion of Atrial Fibrillation/Flutter** Dofetilide is indicated for the conversion of atrial fibrillation and atrial flutter to normal sinus rhythm. Dofetilide has not been shown to be effective in patients with paroxysmal atrial fibrillation.	**Contraindications:** Dofetilide is contraindicated in patients with congenital or acquired long QT syndromes. Dofetilide should not be used in patients with a baseline QT interval or QTc >440 msec (500 msec in patients with ventricular conduction abnormalities). Dofetilide is also contraindicated in patients with severe renal impairment (calculated creatinine clearance <20 mL/min).The concomitant use of verapamil or the cation transport system inhibitors cimetidine, trimethoprim (alone or in combination with sulfamethoxazole), or ketoconazole with Dofetilide is contraindicated, as each of these drugs cause a substantial increase in dofetilide plasma concentrations. In addition, other known inhibitors of the renal cation transport system such as prochlorperazine, dolutegravir and megestrol should not be used in patients on Dofetilide.The concomitant use of hydrochlorothiazide (alone or in combinations such as with triamterene) with Dofetilide is contraindicated because this has been shown to significantly increase dofetilide plasma concentrations and QT interval prolongation **Side Effects:** The most frequent adverse events were headache, chest pain, and dizziness.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		l) Dofetilide 250mcg Capsule Dofetilide USP 0.250mg **Antiarrhythmic**	Do	**Do**	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	UniMed & UniHealth Manufacturers Ltd. Gazipur, Bangladesh	m) Sofosbuvir 400mg + Ledipasvir 90mg Tablet Sofosbuvir INN 400mg + Ledipasvir INN 90mg **Antiviral**	It is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults	**Contraindication**: None **Side-effects:** The most common adverse reactions (incidence greater than or equal to 10%, all grades) observed with treatment with this for 8, 12, or 24 weeks are fatigue and headache.	Sofosbuvir 400mg Tablet	USFDA	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
		n) Chlorhexidine Digluconate 7.1% w/v Solution **Chlorhexidine Digluconate Solution (20%) BP 35.500gm eq. to Chlorhexidine Digluconate 7.100gm/100ml** **Antiseptic**	Chlorhexidine Gluconate 4% aq. Solution is an antimicrobial preparation for pre-operative surgical hand disinfection, antiseptic handwashing on the ward and pre-operative and post-operative skin antisepsis for patients undergoing elective surgery.	**Contraindications**: Known hypersensitivity to the product or any of its components, especially in those with a history of possible chlorhexidine-related allergic reactions Chlorhexidine is known to induce hypersensitivity, including eneralized allergic reactions and anaphylactic shock. Very Common (≥ 1/10); Common (≥ 1/100, < 1/10); Uncommon (≥ 1/1,000, < 1/100); Rare (≥ 1/10,000, < 1/1,000); Very rare (< 1/10,000); not known (cannot be estimated from the available data). Skin and subcutaneous tissue disorders: Frequency not known. Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters. Immune system disorders: Frequency not known: Hypersensitivity including anaphylactic shock. **Adverse Reaction:** Very Common (≥ 1/10); Common (≥ 1/100, < 1/10); Uncommon (≥ 1/1,000, < 1/100); Rare (≥ 1/10,000, < 1/1,000); Very rare (< 1/10,000); not known (cannot be estimated from the available data). Skin and subcutaneous tissue disorders: Frequency not known: Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters. Immune system disorders: Frequency not known: Hypersensitivity including anaphylactic shock.	4% Solution		Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	UniMed & UniHealth Manufacturers Ltd. Gazipur, Bangladesh	o) Calcium Dobesilate 500mg Capsule Calcium Dobesilate INN 500mg **Vasoprotective agent**	It is recommended as the vascular treatment of choice in diabetic retinopathy. It has been used with good effect as a haemostatic during surgical procedures in otorhinolaryngology, ophthalmology and dentistry. It has also shown benefits in chronic venous insufficiency and haemorrhoids.	**Contraindications:** There are no known contra-indications but on general principles Calcium Dobesilate capsules should not be administered during the first trimester of pregnancy. **Side-effects and special precautions:** Rarely in sensitive persons some nausea or gastric discomfort may occur but this rapidly disappears if the dose is decreased.	New	Switzerland	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		p) Lyophilized Bacterial Lysates 50mg Sublingual Tablet Lyophilized Bacterial Lysates INN 50mg (Lyophilized Bacterial Lysates of Staphylococcus aureus, Streptococcus pyogenes and viridans, Klebsiella pneumonia and ozaenae, Haemophilus influenzae, Neisseria catarrhalis Diplococcus pneumonia: 7 mg and 43mg of which corresponded to lyophilization substrate: Glycine) **Bacterial Lysate**	Immunotherapy: chronic upper respiratory and lung infections tree acute, subacute or recurrent. As immunomodulator, Bacterial Lysates reduce the number and severity of episodes of infection, also making prophylaxis on recurrences. The product can if necessary be associated with other therapies (antibiotics, mucolytics).	**Contraindications:** Hypersensitivity to the components of Bacterial Lysates. **Adverse reactions:** To date, no adverse reactions have been reported due to the use of Bacterial Lysates. In the event of an undesirable reaction, consult a doctor immediately.	New	Italy, Poland	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbvwiK bvg		wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
3.	Aristopharma Ltd.	a)	Empagliflozin 10 mg Film Coated Tablet Empagliflozin INN 10 mg **Antidiabetic**	It is a sodium-glucose cotransporter 2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Limitation of Use:** Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis	**Contraindication:** History of serious hypersensitivity reaction to Empagliflozin. Severe renal impairment, end-stage renal disease, or dialysis. **Side-effect:** The most common adverse reactions associated with Empagliflozin (5% or greater incidence) were urinary tract infections and female genital mycotic infections.	New	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK Kiv nj |
		b)	Empagliflozin 25 mg Film Coated Tablet Empagliflozin INN 25 mg **Antidiabetic**	Do	Do	New	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK Kiv nj |
		c)	Alteplase (Injectable Grade) 100 mg (58 million IU) /Vial Lyophilized Injection Alteplase (Injectable Grade) USP 100mg (58 million IU)/Vial **Fibrinolytic Drug**	It is a tissue plasminogen activator (tPA) indicated for the treatment of Acute Ischemic Stroke (AIS), Acute Myocardial Infarction (AMI) to reduce mortality and incidence of heart failure. Limitation of Use in AMI: the risk of stroke may be greater than the benefit in patients at low risk of death from cardiac causes. Acute Massive Pulmonary Embolism (PE) for lysis.	**Contraindications:** **General** Active internal bleeding, Recent intracranial or intraspinal surgery or serious head trauma. Intracranial conditions that may increase the risk of bleeding, Bleeding diathesis. Current severe uncontrolled hypertension. ***Acute Ischemic Stroke*** Current intracranial hemorrhage. Subarachnoid hemorrhage. ***Acute Myocardial Infarction or Pulmonary Embolism*** • History of recent stroke. **Side-Effect:** The most frequently occurring adverse reaction (> 5%) is bleeding.	10mg, 20mg & 50mg/Vial Lyophilized Injection	USFDA	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvMvwiK bvg		wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Aristopharma Ltd.	d)	Metronidazole 400mg + Diloxanide Furoate 500mg Film Coated Tablet Metronidazole BP 400mg + Diloxanide Furoate INN 500mg **Anti Amoebiasis & Anti Giardiasis**	It is indicated in the treatment of acute and chronic intestinal amoebiasis, including the amoebic cyst carrier's hepatitis, amoebic liver abscess, and other systemic infections caused by E. histolytica and giardiasis.	Contra-indications: Hypersensitivity to any of the components, blood dyscrasias, active CNS disease, serious neurological disease, seizures, severe hepatic failure, prennancy (1st trimester), lactation, chronic alcoholism, children<2 years. Side-effect : The common side effects are nausea, headaches, loss of appetite, a metallic taste, flatulence, vomiting and rash. Serious side effects are rare and include seizures and damage of nerves resulting in numbness and tingling of extremities, peripheral neuropathy.	Metronidazole BP 400mg Tablet, Diloxanide Furoate 500mg Tablet		c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj
		e)	Levocloperastine Fendizoate 708mg/100ml Oral Suspension Levocloperastine Fendizoate INN 708mg/100ml **Antitussive**	Treatment of cough associated with acute or chronic respiratory illness and of any other etiology	**Contraindications:** Hypersensitivity to one of the product components. Due to a lack of studies in the 0 to 2 year age band we recommend against using the medicine on young infants. It is generally not recommended during pregnancy. **Side-effect:** No signs or symptoms that can be connected to a central effect of the sedative or stimulating type have been found at therapeutic doses.	New		c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj
		f)	L-Methylfolate 15mg Tablet L-methylfolate Calcium INN 16.425mg eq.to L-methylfolate 15mg **Vitamin**	L-methylfolate is recommended for the dietary supplementation of folic acid in individuals who have suboptimal L-methylfolate levels in the CSF, Plasma, or red blood cells and for general nutritional support. It is also used in people with major depressive disorder (MDD) who has folate deficiency, or in people with schizophrenia who have hyperhomocysteinemia related to folate deficiency	**Contraindications:** L-methylfolate is contraindicated in patients with a known hypersensitivity to any of ingredients contained in the product. **Side-effect:** No common side effects have been reported with L-methylfolate. Seek medical attention right away if any of these severe allergic reactions such as rash; hives; itching; difficulty breathing ; tightness in the chest; swelling of the mouth, face, lips, or tongue occurs.	New		c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †Rvbv‖iK bvg		‖b‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UK‖bK`vj mve-K‖g‖Ui 63 Zg mfvi ‖m×vš	mfvi ‖m×vš
	Aristopharma Ltd.	g)	Betamethasone 0.050gm + Clotrimazole 1.0gm + Gentamicin 0.1gm/100gm Topical Cream Betamethasone Dipropionate USP 0.064gm eq. to Betamethasone 0.050g + Clotrimazole USP 1.0gm + Gentamicin Sulfate USP 0.1693gm eq. to Gentamicin 0.1gm/100gm **Corticosteroid + Anfungal + Antibiotic**	This association is indicated for the relief of inflammatory manifestations of dermatosis responsive to corticotherapy, complicated by secondary infections caused by organisms sensitive to the components of this dermatological preparation or when the possibility of such infection is suspected.	**Contraindications:** Use of this formula must be avoided in patients with hypersensitivity to any of the ingredients of the formula. **Side-Effects:** In very rare cases adverse reactions to treatment have been reported, such as hypochromia, burning, erythema, exudation and pruritus. The following local adverse reactions have also been described with local corticosteroid use, especially when used under occlusive dressings: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation. Adverse reactions attributed to clotrimazole include: rash, itching, blistering, peeling, edema, itching and general irritation of the skin.	Betamethasone 0.05% + Clotrimazole 1% Cream, Betamethasone 0.5% + Gentamicin 0.1% Cream		Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |
		h)	Ubiquinol 100mg + Vitamin B6 10mg Tablet Ubiquinol Acetate INN 115mg eq.to Ubiquinol 100mg + Vitamin B6 (as Pyridoxine Hydrochloride) BP 10mg **Vitamin**	Ubiquinol is indicated for HMG CoA reductase inhibitor mediated decreased level of Coenzyme Q10 in blood, drug induced myopathy, protects body against free radial damage with its antioxidant property, adjuvant therapy in cardiovascular disease especially in angina and congestive heard failure, immune system depression, cognitive decline, management of periodontal disease. Vitamin B6 is generally uses in pyridoxine deficiency, pyridoxine depended seizures, metabolic disorders, neurotoxicity, mushroom toxicity.	Contra-indications: Ubiquinol and Vitamin B6 are contraindicated in patients with a Known hypersensitivity to any of the ingredients contained in these products. Side-effects: Ubiquinol is well tolerated and having no significant side effects. Mild gastro intestinal symptoms such as nausea, diarrhea and epigastric distress have been reported, particularly with higher doses (200 mg or more daily). Vitamin B6 is usually non toxic, adverse neurologic effects, nausea, headache, paresthesia, somnolence, increased serum AST, and decreased serum folic acid concentration.	New		c‡qvRb ‡bB ‖eavq Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB ‖eavq Av‡e`b bvgÄyi Kiv nj |
		i)	Mineral Oil 3.0gm + White Petrolatum 94gm/100gm Sterile Ophthalmic Ointment Mineral Oil BP 3.0g + White Petrolatum BP 94.0gm/100g	This combination drug is indicated for the temporary relief of burning, irritation and discomfort due to dryness of the eye or due to exposure to wind or sun.	**Contraindications:** Hypersensitivity to mineral oil or white petrolatum or to any ingredient of this Product. **Side-effect:** The most common side effects are skin rash, itching or hives, swelling of the face, lips, or tongue, change in vision, eye irritation or redness & eye pain.	New		c‡qvRb ‡bB ‖eavq Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB ‖eavq Av‡e`b bvgÄyi Kiv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
04	Pharmasia Limited	a) Empagliflozin 10mg Tablet Empagliflozin INN 10mg **Antidiabetic**	It is a sodium-glucose co-transporter 2 (SGLT2) inhibitor Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Limitation of Use:** Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	**Contraindication:** History of serious hypersensitivity reaction to Empagliflozin. Severe renal impairment, end-stage renal disease, or dialysis **Side Effects:** The most common adverse reactions associated wit (5% or greater incidence) were urinary tract infections and female genital mycotic infections.	New	USFDA	c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv nj
		b) Empagliflozin 25 Tablet Empagliflozin INN 25 **Antidiabetic**	It is a sodium-glucose co-transporter 2 (SGLT2) inhibitor Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Limitation of Use:** Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	**Contraindication:** History of serious hypersensitivity reaction to Empagliflozin. Severe renal impairment, end-stage renal disease, or dialysis **Side Effects:** The most common adverse reactions associated wit (5% or greater incidence) were urinary tract infections and female genital Mycotic infections.	New	USFDA	c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv nj
		c) Dapagliflozin 5mg + Metformin HCl 500mg Extended Release Tablet Dapagliflozin Propanediol INN 6.16mg eq. to 5mg Dapagliflozin + Metformin HCl BP 500mg **Antidiabetic**	It is a combination of dapagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor, and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate. **Limitation of use:** Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	**Contraindication:** Moderate to severe renal impairment. History of serious hypersensitivity to dapagliflozin or hypersensitivity to metformin hydrochloride. Metabolic acidosis, including diabetic ketoacidosis. **Side Effects:** The most common adverse reactions associated with Dapagliflozin 5mg + Metformin HCl 500mg Extended Release Tablet (5% or greater incidence) were female genital mycotic infection, nasopharyngitis, urinary tract infection, diarrhea, and headache. Adverse reactions reported in >5% of patients treated with metformin extended-release and more commonly than in patients treated with placebo are: diarrhea and nausea/vomiting.	Dapagliflozin 5mg Tablet Metformin HCl 500mg Tablet	USFDA	c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †Rvbv‡iK bvg		wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Pharmasia Limited	d)	Dapagliflozin 5mg + Metformin HCl 1000mg Extended Release Tablet Dapagliflozin Propanediol INN 6.16mg eq. to 5mg Dapagliflozin + Metformin HCl BP 1000mg **Antidiabetic**	It is a combination of dapagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor, and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate. **Limitation of use:** Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	**Contraindication:** Moderate to severe renal impairment. History of serious hypersensitivity to dapagliflozin or hypersensitivity to metformin hydrochloride. Metabolic acidosis, including diabetic ketoacidosis. **Side Effects:** The most common adverse reactions associated with Dapagliflozin 5mg + Metformin HCl 1000mg Extended Release Tablet (5% or greater incidence) were female genital mycotic infection, nasopharyngitis, urinary tract infection, diarrhea, and headache. Adverse reactions reported in >5% of patients treated with metformin extended-release and more commonly than in patients treated with placebo are: diarrhea and nausea/vomiting.	Dapagliflozin 5mg Tablet Metformin HCl 1000mg Tablet	USFDA	c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv nj
		e)	Aliskiren 150 mg Aliskiren + Amlodipine 5mg + Hydrochlorothiazide 12.50mg Tablet Aliskiren Hemifumarate INN 165.80mg eq. to 150mg Aliskiren + Amlodipine Besilate BP 6.94mg eq. to 5mg Amlodipine + Hydrochlorothiazide USP 12.50mg **Antihypertensive**	It is a combination of aliskiren, a renin inhibitor, amlodipine besylate, a dihydropyridine calcium channel blocker, and hydrochlorothiazide (HCTZ), a thiazide diuretic. It is indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Not indicated for initial therapy.	**Contraindication:** Do not use with angiotensin receptor blockers (ARBs) or ACE inhibitors (ACEI) in patients with diabetes, Anuria, Hypersensitivity to sulfonamide-derived drugs or to any of the components **Side Effects:** The most common adverse events (incidence ≥2%) are: peripheral edema, dizziness, headache and nasopharyngitis.	Aliskiren 150 mg+ Hydrochlorothiazide 12.5 mg Tablet Amlodipine 5 mg Tab.	USFDA	c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv nj
		f)	Aliskiren 300mg Aliskiren + Amlodipine 5mg + Hydrochlorothiazide 25mg Tablet Aliskiren Hemifumarate INN 331.60mg eq. to 300mg Aliskiren + Amlodipine Besilate BP 6.94mg eq. to 5mg Amlodipine + Hydrochlorothiazide USP 25mg **Antihypertensive**	It is a combination of aliskiren, a renin inhibitor, amlodipine besylate, a dihydropyridine calcium channel blocker, and hydrochlorothiazide (HCTZ), a thiazide diuretic. It is indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Not indicated for initial therapy.	**Contraindication:** Do not use with angiotensin receptor blockers (ARBs) or ACE inhibitors (ACEI) in patients with diabetes, Anuria, Hypersensitivity to sulfonamide-derived drugs or to any of the components **Side Effects:** The most common adverse events (incidence ≥2%) are: peripheral edema, dizziness, headache and nasopharyngitis.	Aliskiren 150 mg+ Hydrochlorothiazide 12.5 mg Tablet Amlodipine 5 mg Tab.	USFDA	c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
05	Nuvista Pharma Ltd.	a) Suvorexant 5mg Tablet Suvorexant INN 5mg **Orexin receptor antagonist**	It is an orexin receptor antagonist indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.	**Contraindication:** Do not use in patients with narcolepsy. **Side Effect:** The most common adverse reaction (reported in 5% or more of patients treated with it and at least twice the placebo rate) with it was somnolence.	New	USFDA	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyi Kiv nj |
		b) Suvorexant 10mg Tablet Suvorexant INN 10mg **Orexin receptor antagonist**	It is an orexin receptor antagonist indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.	**Contraindication:** Do not use in patients with narcolepsy. **Side Effect:** The most common adverse reaction (reported in 5% or more of patients treated with it and at least twice the placebo rate) with it was somnolence.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |
		c) Vorapaxar Sulfate 2.5mg Tablet Vorapaxar Sulfate INN 2.5mg eq. to 2.08mg Vorapaxar **Antiplatelet Drugs**	Vorapaxar is a protease-activated receptor-1 (PAR-1) antagonist, indicated for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD). Vorapaxar has been shown to reduce the rate of a combined endpoint of cardiovascular death, MI, stroke, and urgent coronary revascularization (UCR).	**Contraindication:** Like other antiplatelet agents, it increases the risk of bleeding. Avoid use with strong CYP3A Inhibitors or inducers. **Side Effect:** Bleeding, including life-threatening and fatal bleeding, is the most commonly reported adverse reaction.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |
		d) Dapagliflozin Propanediol 5mg + Metformin Hydrochloride Extended-Release 500mg Tablet Dapagliflozin Propanediol INN 5mg + Metformin Hydrochloride BP 500mg **Antidiabetic**	Dapagliflozin and metformin HCl extended-release is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate. **Limitation of use:** Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	**Contraindication:** Moderate to severe renal impairment. History of serious hypersensitivity to dapagliflozin or hypersensitivity to metformin hydrochloride. Metabolic acidosis, including diabetic ketoacidosis. **Side Effect:** The most common adverse reactions associated with Dapagliflozin and metformin HCl extended-release Tablet (5% or greater incidence) were female genital mycotic infection, nasopharyngitis, urinary tract infection, diarrhea, and headache Adverse reactions reported in >5% of patients treated with metformin extended release and more commonly than in patients treated with placebo are: diarrhea and nausea/vomiting.	Dapagliflozin 5mg Tablet Metformin 500mg Tablet	USFDA	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyi Kiv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Nuvista Pharma Ltd.	e) Dapagliflozin Propanediol 10mg + Metformin Hydrochloride Extended-Release 1000mg Tablet Dapagliflozin Propanediol INN 10mg + Metformin Hydrochloride BP 1000mg **Antidiabetic**	Dapagliflozin and metformin HCl extended-release is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate. **Limitation of use:** Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	**Contraindication:** Moderate to severe renal impairment. History of serious hypersensitivity to dapagliflozin or hypersensitivity to metformin hydrochloride. Metabolic acidosis, including diabetic ketoacidosis. **Side Effect:** The most common adverse reactions associated with Dapagliflozin and metformin HCl extended-release Tablet (5% or greater incidence) were female genital mycotic infection, nasopharyngitis, urinary tract infection, diarrhea, and headache Adverse reactions reported in >5% of patients treated with metformin extended release and more commonly than in patients treated with placebo are: diarrhea and nausea/vomiting.	Dapagliflozin 5mg Tablet Metformin 1000mg Tablet	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj |
		f) Lurasidone Hydrochloride 20mg Tablet Lurasidone Hydrochloride INN 20mg **Antipsychotic agent**	**Adults** Schizophrenia: lurasidone HCl is indicated for the management of the manifestations of Schizophrenia. The antipsychotic efficacy of lurasidone hcl was established in short-term (6-week) controlled trials The efficacy of lurasidone HCL in long-term use, that is, for more than 6 weeks, has not been systematically evaluated in controlled trials of patients with manifestations of schizophrenia. Depressive Episodes Associated with Bipolar I Disorder lurasidone HCl is indicated as monotherapy or as adjunctive therapy with lithium or valproate for the acute management of depressive episodes associated with bipolar I disorder. The efficacy of lurasidone HCl for long-term use, that is, for more than 6 weeks, has not been systematically evaluated in controlled studies. The physician who elects to use LURASIDONE HCl for extended periods should periodically re-evaluate the long term usefulness of the drug for the individual patient. Geriatrics (>65 years of age): It is not indicated in elderly patients with dementia. The safety and efficacy of LURASIDONE HCl in patients 65 years of age or older has not been established. Pediatrics (<18 years of age): Safety and efficacy in pediatric patients have not been evaluated and its use is not recommended.	**Contraindication:** Known hypersensitivity to Lurasidone HCl or any components in the formulation. **Side Effect:** Increased Mortality in Elderly Patients with Dementia-Related Psychosis. Cerebrovascular Adverse Reactions, Including Stroke, in Elderly Patients with Dementia-related Psychosis. Neuroleptic Malignant Syndrome. Tardive Dyskinesia. Metabolic Changes (Hyperglycemia and Diabetes Mellitus, Dyslipidemia, and Weight Gain) Hyperprolactinemia, Seizures	40mg Tablet	USFDA	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |

bs	c¯ZKvi‡Ki bvg		JI‡ai bvg I †RvMvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Nuvista Pharma Ltd.	g)	Perindopril Arginine 7mg + Amlodipine 5mg Tablet Perindopril Arginine INN 7mg + Amlodipine BP 5mg **Antihepertensive**	It is a combination of perindopril, an angiotensin converting enzyme inhibitor, and amlodipine, a dihydropyridine calcium channel blocker, indicated for the treatment of hypertension to lower blood pressure: In patients not adequately controlled with monotherapy , As initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.	**Contraindication**: History of angioedema, or hypersensitivity to any ACE inhibitor or to amlodipine. Do not use aliskiren with it in patients with diabetes. **Side Effects:** The most common adverse reactions were edema (7.2%), cough (3.2%), headache (2.5%), and dizziness (2.5%).	Perindopril Erbumine 2 mg, 4 mg & 8 mg Tablet Amlodipine 5 mg Tablet	USFDA	c‡qvRb ‡bB wewfbœ Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wewfbœ Av‡e`b bvgÄyi Kiv nj
		h)	Perindopril Arginine 14mg + Amlodipine 10mg Tablet Perindopril Arginine INN 14mg + Amlodipine BP 10mg **Antihepertensive**	It is a combination of perindopril, an angiotensin converting enzyme inhibitor, and amlodipine, a dihydropyridine calcium channel blocker, indicated for the treatment of hypertension to lower blood pressure: In patients not adequately controlled with monotherapy, As initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.	**Contraindication**: History of angioedema, or hypersensitivity to any ACE inhibitor or to amlodipine. Do not use aliskiren with it in patients with diabetes. **Side Effects:** The most common adverse reactions were edema (7.2%), cough (3.2%), headache (2.5%), and dizziness (2.5%).	Perindopril Erbumine 2 mg, 4 mg & 8 mg Tablet Amlodipine 5 mg Tablet	USFDA	c‡qvRb ‡bB wewfbœ Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wewfbœ Av‡e`b bvgÄyi Kiv nj
6.	Healthcare Pharmaceuticals Limited	a)	Ceftriaxone 2gm + Tazobactam 250 mg IM/IV injection Ceftriaxone Sodium 2777.76 mg eq. Ceftriaxone USP 2 gm + Tazobactam USP 250 mg **Antibiotic (Cephalosporin)**	• Lower Respiratory Tract Infections • Acute Bacterial Ottitis Media • Skin and Skin Structure Infections • Urinary Tract Infections • Uncomplicated Gonorrhea • Pelvic Inflammatory Disease • Bacterial Septicemia • Bone and Joint Infections • Intra-Abdominal Infections • Meningitis • Surgical Prophylaxis	**Contra-indication**: Contraindicated in patients with known allergy to the cephalosporin or beta lactam class of antibiotics. **Side-effects:** leukopenia anemia, hemolytic anemia, neutropenia, lymphopenia, thrombocytopenia, diarrhea, nausea, vomiting, dysgeusia, moniliasis, vaginitis. Pain, tenderness , Phlebitis rash pruritus, fever or chills, eosinophilia, thrombocytosis,	New		c‡qvRb ‡bB wewfbœ Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wewfbœ Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Healthcare Pharmaceuticals Limited	b) Faropenem 150 mg film coated tablet Faropenem sodium INN 161.55mg eq. to Faropenem 150 mg **Antibiotic**	Upper & lower respiratory tract infections, ENT infections, Genitourinary infections, skin and skin structure infections and Gynaecological infections	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the components of this product or to other drugs in the same class. **Side-effects:** The most frequently reported adverse reactions are diarrhea, abdominal pain, loose bowel movements, nausea and rash.	New		c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj	
		c) Faropenem 200 mg film coated tablet Faropenem sodium INN 215.40 mg eq. to Faropenem 200 mg **Antibiotic**	•Upper & lower respiratory tract infections • ENT infections • Genitourinary infections • skin and skin structure infections •Gynaecological infections	**Contra-indication:** Contraindicated in patients with known hypersensitivity to any of the components of this product or to other drugs in the same class. **Side-effects:** The most frequently reported adverse reactions are diarrhea, abdominal pain, loose bowel movements, nausea and rash.	New		c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj	
		d) Palonosetron 0.5mg + Netupitant 300mg Capsule Palonosetron Hydrochloride INN 0.56mg eq. to Palonosetron 0.5mg + Netupitant INN 300mg **Antiemetic**	It is a fixed combination of netupitant, a substance P/neurokinin 1(NK 1) receptor antagonist, and palonosetron, a serotonin 3 (5-HT3) receptor Antagonist indicated for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Oral palonosetron prevents nausea and vomiting during the acute phase and netupitant prevents nausea and vomiting during both the acute and delayed phase after cancer chemotherapy.	Contraindications: None Side-effects: Most common adverse reactions are headache, asthenia, dyspepsia, fatigue, constipation and erythema.	Palonosetron 0.5mg tablet & Palonosetron 0.075 mg & 0.25 mg IV injection	USFDA	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj	

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Healthcare Pharmaceuticals Limited	e) Darbepoetin alfa 60mcg/0.30ml PFS injection Darbepoetin Sterile solution Ph. Grade 0.30 ml (contains Darbopoetin alfa INN 60 mcg)/0.3ml **Hematopoietic**	It is an erythropoiesis-stimulating agent (ESA) indicated for the treatment of anemia due to: • Chronic Kidney Disease (CKD) in patients on dialysis and patients not on dialysis. • The effects of concomitant myelosuppressive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy. **Limitations of Use** Darbepoetin has not been shown to improve quality of life, fatigue, or patient well-being. Darbepoetin is not indicated for use: • In patients with cancer receiving hormonal agents, biologic products, or radiotherapy, unless also receiving concomitant myelosuppressive chemotherapy. • In patients with cancer receiving yelosuppressive chemotherapy when the anticipated outcome is cure. • As a substitute for RBC transfusions in patients who require immediate correction of anemia.	**Contra-indication:** • Uncontrolled hypertension • PRCA (pure red cell aplasia) that begins after treatment with erythropoietin protein drugs • Serious allergic reactions to Darbepoetin **Side-effects:** Patients with CKD: Adverse reactions in ≥ 10% of Darbepoetin-treated patients in clinical studies were hypertension, dyspnea, peripheral edema, cough, and procedural hypotension. Cancer Patients Receiving Chemotherapy: Adverse reactions in 1% of Darbepoetin-treated patients in clinical studies were abdominal pain, edema, and thrombovascular events.	25mcg/0.42 ml; 40mcg/0.4 ml	USFDA BNF-69 Page-668	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
		f) Darbepoetin alfa 100mcg/0.50ml PFS Injection Darbepoetin Sterile solution Ph. Grade 0.50 ml (contains Darbopoetin alfa INN 100 mcg)/0.50ml **Hematopoietic**	Do	Do	25mcg/0.42 ml 40mcg/0.4 ml	USFDA BNF-69 Page-668	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Healthcare Pharmaceuticals Limited	g) Calcium 600 mg + Vitamin D_3 400 IU + Magnesium 40 mg + zinc 7.5 mg+ Copper 1 mg +Manganese 1.8 mg + Boron 0.25 mg Effervescent Tablet Calcium carbonates USP 1500mg eq. to 600 mg elemental calcium + Dry Vitamin D3 100 cws ph. Grade 4.80 mg eq. to 400 IU vitamin D3 + Heavy Magnesium oxide BP 69.64 mg eq. To 40 mg magnesium + Zinc oxide (Powder) BP 9.8 mg eq. to 7.5 mg Zinc + Manganese sulphate monohydrate BP 5.81 mg eq. to 1.8 mg Manganese + Boron Citrate 5.0% Ph. Grade 5.25 mg eq. to 0.25 mg Boron + Cupric Oxide Ph. Grade 1.32 mg eq. to 1 mg Copper **Vitamin+Minerals**	Osteoporosis, Postmenopausal Osteoporosis where extra care is needed for heart, muscle, and nerves, Osteomalacia, Rickets, for normal growth and muscle strength, Pregnancy and lactation	**Contra-indication:** Hypercalcaemia. **Side-effects:** Hypersensitivity, nausea/vomiting, constipation.	Calcium 600 mg+ Vitamin D_3 (Cholecalciferol) **200** IU + Magnesium 40 mg+ zinc 7.5 mg+ Copper 1 mg + Manganese 1.8 mg + Boron 0.25 mg Tablet		Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
		h) Erythropoietin alfa EP 1000IU/0.5 ml Human Recombinant Erythropoietin ready to fill sterile solution Pharma. Grade **Hematopoietic**	Anemia due to Chronic kidney disease in paediatric and adult patients on haemodialysis and adult patients on peritoneal dialysis.	**Contraindication:** • Uncontrolled hypertension • PRCA (pure red cell aplasia) that begins after treatment with erythropoietin protein drugs • Serious allergic reactions to Erythropoietin alfa **Side-effects:** Chest pain, fever**,** headache**,** increased blood pressure**,** shortness of breath**,** swelling of the face, fingers, ankles, feet, or lower legs**,** weight gain	2000 IU/0.5 ml; 3000 IU/0.75 ml; 5000 IU/0.5 ml & 10,000 IU/1 ml Injection	EMA	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Healthcare Pharmaceuticals Limited	i) Tenecteplase 50 mg/ Vial Lyophilized Powder for injection Tenecteplase INN 50 mg/Vial **Thrombolytic Enzyme**	It is indicated for use in the reduction of mortality associated with acute myocardial infarction. Treatment should be initiated as soon as possible after the onset of acute myocardial infarction symptoms.	**Contraindications:** Tenecteplase therapy in patients with acute myocardial infarction is contraindicated in the following situations because of an increased risk of bleeding: Active internal bleeding, History of cerebrovascular accident, Intracranial or intraspinal surgery or trauma within 2 months, Intracranial neoplasm, arteriovenous malformation, or aneurysm, Known bleeding diathesis, Severe uncontrolled hypertension. **Side-effects:** The most frequent adverse reaction associated with Tenecteplase is bleeding. Should serious bleeding occur, concomitant heparin and antiplatelet therapy should be discontinued. Death or permanent disability can occur in patients who experience stroke or serious bleeding episodes. For Tenecteplase treated patients in ASSENT 2, the incidence of intracranial hemorrhage was 0.9% and total stroke was 1.8%. The incidence of all strokes, including intracranial bleeding.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		j) Palbociclib 75mg Capsule Palbociclib INN 75mg **Anticancer**	It is a kinase inhibitor indicated in combination with letrozole for the treatment of postmenopausal women with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease. This indication is approved under accelerated approval based on progression-free survival (PFS). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.	**Contraindications:** None **Side-effects:** Most common adverse reactions (incidence ≥10%) were neutropenia, leukopenia, fatigue, anemia, upper respiratory infection, nausea, stomatitis, alopecia, diarrhea, thrombocytopenia, decreased appetite, vomiting, asthenia, peripheral neuropathy, and epistaxis.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		k) Palbociclib100mg Capsule Palbociclib INN 100mg **Anticancer**	Do	Do	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		l) Palbociclib125mg Capsule Palbociclib INN 125mg **Anticancer**	Do	Do	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
7.	**Navana Pharmaceuticals Ltd.**	a) Suvorexant 5mg Tablet Suvorexant INN 5mg **Orexin receptor antagonist**	Suvorexant is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.	**Contraindications:** Suvorexant is contraindicated in patients with narcolepsy. **Side Effects:** The following serious adverse reactions are discussed in greater detail in other sections: CNS depressant effects and daytime impairment; abnormal thinking and behavioral changes; worsening of Depression/Suicidal ideation; Sleep paralysis, hypnagogic/hypnopompic hallucinations, cataplexy-like symptoms	New	USFDA	c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv †h‡Z cv‡i |	c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv nj |
		b) Suvorexant 10mg Tablet Suvorexant INN 10mg **Orexin receptor antagonist**	Do	Do	New	USFDA	Abyôv`b K iv †h‡Z cv‡i |	Abyôv`b K iv nj |
		c) Suvorexant 15mg Tablet Suvorexant INN 15mg **Orexin receptor antagonist**	Do	Do	New	USFDA	c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv †h‡Z cv‡i |	c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv nj |
		d) Dapagliflozin 5mg + Metformin HCl ER 500mg Tablet Dapagliflozin Propanediol monohydrate In House 6.15mg eq. to 5mg Dapagliflozin + Metformin HCl BP 500mg **Antidiabetic**	It is a combination of dapagliflozin, a sodium-glucose cotransporter 2 (SGLT2) inhibitor, and metformin, a biguanide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both dapagliflozin and metformin is appropriate. **Limitation of use:** Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	**Contraindication:** Moderate to severe renal impairment. History of serious hypersensitivity to dapagliflozin or hypersensitivity to metformin hydrochloride. Metabolic acidosis, including diabetic ketoacidosis. **Side Effects:** The most common adverse reactions associated with Dapagliflozin 5mg + Metformin HCl 500mg Extended Release Tablet (5% or greater incidence) were female genital mycotic infection, nasopharyngitis, urinary tract infection, diarrhea, and headache. Adverse reactions reported in >5% of patients treated with metformin extended-release and more commonly than in patients treated with placebo are: diarrhea and nausea/vomiting.	Dapagliflozin 5mg Tablet Metformin HCl 500mg ER Tablet	USFDA	c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv †h‡Z cv‡i |	c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Navana Pharmaceuticals Ltd.	e) Empagliflozin 10mg + Linagliptin 5mg Empagliflozin INN 10mg+ Linagliptin INN 5mg **Antidiabetic**	It is a sodium-glucose co-transporter 2 (SGLT2) inhibitor and dipeptidyl peptidase-4 (DPP-4) inhibitor combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and linagliptin is appropriate. **Limitations of use:** • Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. Has not been studied in patients with a history of pancreatitis	**Contraindications:** ➢ Severe renal impairment, end-stage renal disease, or dialysis ➢ History of hypersensitivity reaction to linagliptin, such as anaphylaxis, angioedema, exfoliative skin conditions, urticaria, or bronchial hyperreactivity. ➢ History of serious hypersensitivity reaction to empagliflozin **Side effects:** The most common adverse reactions associated with GLYXAMBI (a 5% or greater incidence) were urinary tract infections, nasopharyngitis, and upper respiratory tract infections.	Linagliptin 5mg Tablet	USFDA	*c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i|*	*c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj|*
		f) Empagliflozin 25mg+ Linagliptin 5mg Empagliflozin INN 25mg + Linagliptin INN 5mg **Antidiabetic**	Do	Do	Linagliptin 5mg Tablet	USFDA	*c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i|*	*c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj|*
		g) Sucroferric Oxyhydroxide 2500mg Chewable Tablet Sucroferric Oxyhydroxide 2500mg eq.to. Elemental Iron 500mg **Phosphate Binder**	It is a phosphate binder indicated for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis.	**Contraindications:** None; **Side Effects:** In a parallel design, fixed-dose study of 6 weeks duration, the most common adverse drug reactions to Velphoro chewable tablets in hemodialysis patients included discolored feces (12%) and diarrhea (6%).	New	USFDA	*Abyfgv`b Kiv †h‡Z cv‡i|*	*Abyfgv`b Kiv nj|*

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
8.	Globe Pharmaceuticals Ltd., BSCIC Industrial Estate Begumgonj, Noakhalia	a) Ceftazidime 2 gm + Avibactam 0.5 gm/Vial Sterile powder for solution for Infusion Ceftazidime Pentahydrate USP 2.635mg eq. to 2gm Ceftazidime + Avibactam Sodium INN 0.551 gm eq. to 0.500gm Avibactam/Vial **Antibiotic**	For the treatment of patients 18 years or older with following infections caused by the susceptible microorganisms. 1. Complicated intra-abdominal infections (cIAI), used in combination with metronidazole. 2. Complicated Urinary Tract Infections (cUTI) including Pyelonephritis.	**Contraindications:** In patients with known hypersensitivity to the products, Ceftazidime or other Cephalosporin Class. **Side effects:** The reported side effects are vomiting, nausea, constipation and anxiety.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		b) Ceftobiprole 500 mg/Vial Lyophilized powder for solution for Infusion Ceftobiprole Medocaril Sodium INN 666.6 mg eq. to 500mg Ceftobiprole/Vial **Antibiotic**	Ceftobiprole is indicated for the treatment of following infections in adults Hospital-acquired Pneumonia (HAP) and Community-acquired Pneumonia (CAP)	**Contraindications:** Hypersensitivity to the cephalosporin class of antibacterial. Immediate and severe hypersensitivity (e.g. anaphylactic reaction) to any other type of beta-lactam antibacterial agent (e.g. penicillins or carbapenems) **Side effects:** Less frequently reported, but more serious, adverse reactions include thrombocytopenia, agranulocytosis, anaphylaxis, *Clostridium difficile*, colitis, convulsion, agitation (including anxiety, panic attacks and nightmares), and renal failure.	New	MHRA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		c) Dapagliflozin 5 mg + Metformin 500mg ER Tablet Dapagliflozin Propanediol Monohydrate INN 6.15 mg eq. to 5mg Dapagliflozin + Metformin HCl BP 500 mg **Antidiabetic**	It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treated with both Dapagliflozin and Metformin is appropriate. **Limitation of use:** Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis.	**Contraindications:** Moderate to severe renal impairment, Hypersensitivity reactions and metabolic acidosis including diabetic ketoacidosis. **Side effects:** The reported side effects are female genital mycotic infection, nasopharyngitis, UTI, diarrhea and headache.	New	USFDA	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Globe Pharmaceuticals Ltd.,	d) Dapagliflozin 10 mg + Metformin 500mg ER Tablet Dapagliflozin Propanediol Monohydrate INN 12.30mg eq. to 10 mg Dapagliflozin + Metformin HCl BP 500 mg **Antidiabetic**	Do	Do	New	USFDA	c‡qvRb ‡bB wea\q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea\q Av‡e`b bvgÄyi Kiv nj |
		e) Empagliflozin 10 mg FC Tablet Empagliflozin In House 10 mg **Antidiabetic**	Empagliflozin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Limitation of Use:** Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis	**Contraindications:** This drug is contraindicated in patients with history of serious hypersensitivity reaction to Empagliflozin. Severe renal impairment, end-stage renal disease, or dialysis. **Side effects:** The reported side effects are hypotension, hypoglycemia with concomitant use with Insulin and Insulin Secretagogues, urinary tract infections and female genital mycotic infections.	New	USFDA	c‡qvRb ‡bB wea\q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea\q Av‡e`b bvgÄyi Kiv nj |
		f) Empagliflozin 25 mg FC Tablet Empagliflozin In House 25 mg **Antidiabetic**	Empagliflozin is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Limitation of Use:** Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis	**Contraindications:** This drug is contraindicated in patients with history of serious hypersensitivity reaction to Empagliflozin. Severe renal impairment, end-stage renal disease, or dialysis. **Side effects:** The reported side effects are hypotension, hypoglycemia with concomitant use with Insulin and Insulin Secretagogues, urinary tract infections and female genital mycotic infections.	New	USFDA	c‡qvRb ‡bB wea\q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea\q Av‡e`b bvgÄyi Kiv nj |
		g) Phytomenadione (Vitamin K_1) 1mg Soft Gelatin Capsule Phytomenadione BP 1 mg **Vitamin**	Phytomenadione is indicated for the prevention of vitamin K deficiency bleeding in newborn babies.	**Contraindications:** Further doses of Vitamin-K capsules should be avoided to any baby showing evidence of hypersensitivity to any of the constituents. **Side effects:** No adverse effects have been associated with oral administration.	Phytomenadione 2mg/0.2 ml and 10mg/ml injection	MHRA	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg		wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Globe Pharmaceuticals Ltd., BSCIC Industrial Estate Begumgonj, Noakhalia	h)	Suvorexant 10 mg FC Tablet Suvorexant INN 10 mg **Sedative**	Suvorexant is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.	**Contraindications**: Contraindicated in patients with narcolepsy. **Side effects:** The most common adverse reaction in patients treated with Suvorexant somnolence.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		i)	Tofacitinib 5 mg FC Tablet Tofacitinib Citrate In House 8mg eq. to 5 mg Tofacitinib **Disease-modifying Antirheumatic Drugs (DMARDs)**	Tofacitinib is indicated for the treatment of adult patients with moderate to severe active rheumatoid arthritis who have an inadequate response or intolerance to methotrexate. It may be used as monotherapy or in combination with methotrexate or other nonbiologic Disease-Modifying Antirheumatic Drugs (DMARDs). It should not be used in combination with biologic DMARDs or potent immunosuppressants such as azathioprine and cyclosporine.	**Contraindications**: None **Side effects:** The most commonly reported adverse reactions during the first 3 months in controlled clinical trials (occurring in greater than or equal to 2% of patients treated with Tofacitinib monotherapy or in combination with DMARDs) were upper respiratory tract infections, headache, diarrhea and nasopharyngitis.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		j)	Itopride HCl 50mg FC Tablet Itopride HCl INN 50 mg **Prokinetic-Antiemetic**	Itopride HCl is indicated in the treatment of gastrointestinal symptoms of functional, nonulcer dyspepsia (chronic gastritis) i.e, sensation of bloating, early satiety, upper abdominal pain or discomfort, anorexia, heartburn, nausea and vomiting.	**Contraindications**: This drug is contraindicated in patients with history of hypersensitivity to any ingredients of this product. **Side effects:** In clinical trials the most common adverse reactions observed were diarrhea, headache, and abdominal pain. Abnormalities in laboratory data were leucopenia, increased prolactin, increased AST (GOT), and increased ALT (GPT) etc.	New		c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj
9.	Labaid Pharmaceuticals Ltd.	a)	Ezogabine 50 mg Tablet Ezogabine INN 50 mg **Anticonvulsant**	It is a potassium channel opener indicated as adjunctive treatment of partial-onset seizures in patients aged 18 years and older who have responded inadequately to several alternative treatments and for whom the benefits outweigh the risk of retinal abnormalities and potential decline in visual acuity.	**Contraindications:** None **Side Effects:** The most common adverse reactions (incidence ≥4% and approximately twice placebo) are dizziness, somnolence, fatigue, confusional state, vertigo, tremor, abnormal coordination, diplopia, disturbance in attention, memory Impairment, asthenia, blurred vision, gait disturbance, aphasia, dysarthria, and balance disorder. **Box Warnings:** Retinal Abonormalities and potential vision Loss.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Labaid Pharmaceuticals Ltd.	b) Apremilast 10 mg Tablet Apremilast In House 10 mg **Antiinflammatory**	Apremilast is indicated for the treatment of adult patients with active psoriatic arthritis	**Contraindications:** Apremilast is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation **Side Effects:** Adverse reactions reported in patients on Apremilast in clinical studies including extension studies: Immune system disorders: Hypersensitivity Investigations: Weight decrease Gastrointestinal Disorders: Frequent bowel movement, gastroesophageal reflux disease, dyspepsia Metabolism and Nutrition Disorders: Decreased appetite Nervous System Disorders: Migraine Respiratory, Thoracic, and Mediastinal Disorders: Cough Skin and Subcutaneous Tissue Disorders: Rash	New	USFDA	Abyjgvw`b Kiv †h‡Z cv‡i	Abyjgvw`b Kiv nj	
		c) Dantrolene 50 mg Capsule Dantrolene Sodium Hemiheptahydrate USP 59.348mg eq. to Dantrolene 50mg **Skeletal Muscle Relaxant**	In Chronic Spasticity: Dantrolene is indicated in controlling the manifestations of clinical spasticity resulting from upper motor neuron disorders (e.g., spinal cord injury, stroke, cerebral palsy, or multiple sclerosis). It is of particular benefit to the patient whose functional rehabilitation has been retarded by the sequelae of spasticity. Such patients must have presumably reversible spasticity where relief of spasticity will aid in restoring residual function. Dantrolene is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic Disorders. If improvement occurs, it will ordinarily occur within the dosage titration and will be manifested by a decrease in the severity of spasticity and the ability to resume a daily function not quite attainable without Dantrolene. In Malignant Hyperthermia: Oral Dantrolene is also indicated preoperatively to prevent or attenuate the development of signs of malignant hyperthermia in known, or strongly suspect malignant hyperthermia susceptible patients who require anesthesia and/or surgery. Oral Dantrolene should be administered following a malignant hyperthermic crisis to prevent recurrence of the signs of malignant hyperthermia.	**Contraindications:** Active hepatic disease, such as hepatitis and cirrhosis, is a contraindication for use of dantrolene sodium capsules. Dantrolene sodium capsules are contraindicated where spasticity is utilized to sustain upright posture and balance in locomotion or whenever spasticity is utilized to obtain or maintain increased function. **Side Effects:** Very common side effects- Drowsiness, dizziness, weakness, general malaise, fatigue, and diarrhea.	25mg	USFDA	Abyjgvw`b Kiv †h‡Z cv‡i	Abyjgvw`b Kiv nj	

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Labaid Pharmaceuticals Ltd.	d) Dantrolene 100 mg Capsule Dantrolene Sodium Hemiheptahydrate USP 118.697mg eq. to Dantrolene 100mg **Skeletal Muscle Relaxant**	In Chronic Spasticity: Dantrolene is indicated in controlling the manifestations of clinical spasticity resulting from upper motor neuron disorders (e.g., spinal cord injury, stroke, cerebral palsy, or multiple sclerosis). It is of particular benefit to the patient whose functional rehabilitation has been retarded by the sequelae of spasticity. Such patients must have presumably reversible spasticity where relief of spasticity will aid in restoring residual function. Dantrolene is not indicated in the treatment of skeletal muscle spasm resulting from rheumatic Disorders. If improvement occurs, it will ordinarily occur within the dosage titration and will be manifested by a decrease in the severity of spasticity and the ability to resume a daily function not quite attainable without Dantrolene. In Malignant Hyperthermia: Oral Dantrolene is also indicated preoperatively to prevent or attenuate the development of signs of malignant hyperthermia in known, or strongly suspect malignant hyperthermia susceptible patients who require anesthesia and/or surgery. Oral Dantrolene should be administered following a malignant hyperthermic crisis to prevent recurrence of the signs of malignant hyperthermia.	**Contraindications:** Active hepatic disease, such as hepatitis and cirrhosis, is a contraindication for use of dantrolene sodium capsules. Dantrolene sodium capsules are contraindicated where spasticity is utilized to sustain upright posture and balance in locomotion or whenever spasticity is utilized to obtain or maintain increased function. **Side Effects:** Very common side effects- Drowsiness, dizziness, weakness, general malaise, fatigue, and diarrhea.	New	USFDA	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
		e) Vorapaxar 2.08 mg Tablet Vorapaxar sulfate INN 2.5 eq. to 2.08mg Vorapaxar **Platelet aggregation Inhibitor**	Vorapaxar is a protease-activated receptor-1 (PAR-1) antagonist indicated for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD). Vorapaxar has been shown to reduce the rate of a combined endpoint of cardiovascular death, MI, stroke, and urgent coronary revascularization.	**Contraindications:** • Patients with ahistory of stroke or transient ischaemic attack (TIA). • Patients with a history of intracranial haemorrhage (ICH). • Patients with any active pathological bleeding. • Severe hepatic impairment. **Side Effects:** Common side effects in people who is taking Vorapaxar include: Anemia, Depression & Rash.	New	USFDA	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvMvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Labaid Pharmaceuticals Ltd.	f) Zinc Orotate 60 mg Tablet Zinc Orotate Dihydrate INN 65.945 mg eq. to 60mg Zinc Orotate	Cell Regulation, Encourages Normal Blood Sugar Heightens Smell and Taste, Immune Support, Promotes Normal Metabolism	**Contraindications:** None **Side effects:** The most common adverse reactions of oral zinc are nausea, bad taste, diarrhea, vomiting, mouth irritation, and, rarely, mouth sores. Nasal and throat irritation may occur with the zinc spray. There have been case reports of apparent zinc-induced copper deficiency, immune system dysfunction, and myeloneuropathy. An increase in genitourinary symptoms and prostate cancer has been related to zinc supplementation.	New		c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK iv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK iv nj |
		g) Lomitapide 5 mg Capsules Lomitapide INN 5 mg **Lipid Lowering agent**	It is a microsomal triglyceride transfer protein inhibitor indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-highdensity lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH). **Limitations of Use**: The safety and effectiveness of Lomitapide have not been established in patients with hypercholesterolemia who do not have HoFH. The effect of Lomitapide on cardiovascular morbidity and mortality has not been determined.	**Contraindications:** Pregnancy, Concomitant use with strong or moderate CYP3A4 inhibitors. Moderate or severe hepatic impairment or active liver disease including unexplained persistent abnormal liver function tests **Side Effects:** Most common adverse reactions (incidence ≥28%) are diarrhea, nausea, vomiting, dyspepsia, and abdominal pain.	New	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK iv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK iv nj |
		h) Lomitapide 10 mg Capsules Lomitapide INN 10 mg **Lipid Lowering agent**	Do	Do	New	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK iv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK iv nj |
		i) Lomitapide 20 mg Capsule Lomitapide INN 20 mg **Lipid Lowering agent**	Do	Do	New	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK iv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyK iv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Labaid Pharmaceuticals Ltd.	j) Tasimelteon 20 mg Capsule Tasimelteon INN 20mg **Sedative**	Tasimelteon is a melatonin receptor agonist indicated for the treatment of Non-24-Hour Sleep-Wake Disorder (Non-24)	**Contraindications:** None **Side Effects:** The most common side effects (incidence >5% and at least twice as high as on placebo) were headache increased alanine aminotransferase, nightmares or unusual dreams, and upper respiratory or urinary tract infection.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		k) Multivitamins & Multiminerals Tablet Vitamin A Palmitate USP 2667 IU + Colecalciferol (Vitamin D3) BP 200 IU + All-rac-Alpha-Tocopherol BP 10 mg + Sodium Ascorbate USP 68.28 mg eq. to 60 mg Ascorbic Acid + Thiamine Nitrate BP 1.4 mg + Riboflavin (Vitamin B2) USP 1.6 mg + Nicotinamide USP 18mg + Pyridoxine HCl BP 2mg + Folic Acid USP 0.1 mg + Panax Ginseng extract (80% Ginsenosides) BP 50 mg eq. to 40mg Ginsenosides + Cyanocobalamin 1% Pharma Grade 0.1 mg eq.to 0.001 mcg Cyanocobalamin + Biotin BP 0.15 mg + Calcium Hydrogen Phosphate Dihydrate BP 429.3 mg eq. to 100mg Calcium + Dried Ferrous Sulphate BP 27.2 mg Equivalent to 10 mg Iron + Dried Magnesium Sulphate BP 49.53mg eq. to Magnesium 10mg + Zinc Sulphate Monohydrate BP 2.745 mg eq. to Zinc 1mg + Anhydrous Copper Sulphate BP 5.024 mg eq. to 2 mg Copper + Sodium Selenite BP 0.11 mg eq. to 0.05 mg Selenium + Lecithin BP 100mg	It is indicated in the management of fatigue and weakness associated with stress, convalescence, or the symptoms of ageing, impaired general health. As a vitamin and mineral supplement for persons requiring dietary adjuncts, as in convalescence, etc. in the correction of specific vitamin deficiencies.	**Contraindications:** It is contraindicated in patients with disturbances of calcium metabolism (e.g. hypercalcaemia and hypercalciuria), hypervitaminosis A or D, renal insufficiency, concomitant retinoid (e.g. for acne) or vitamin D therapy, haemochromatosis, iron overload syndrome, pregnancy and lactation and in patients with known hypersensitivity to any of the ingredients in the product. **Side Effects:** Nausea, diarrhea, and vomiting.	New		c‡qvRb ‡bB wea¨vq Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea¨vq Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †Rvwbwi‡K bvg		wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
10	Somatec Pharmaceuticals Ltd., Demra, Dhaka	a)	Calcium 333 mg + Magnesium 167mg + Vitamin D3 (Cholecalciferol) 200 IU Calcium Carbonate USP 831.54 mg eq. to 333 mg elemental Calcium + Magnesium Oxide BP eq. to 167 mg Magnesium + Vitamin D3 (Cholecalciferol) USP 200 IU **Minerals+Vitamins**	Maintains strong bones and healthy teeth. Helps prevent osteoporosis to reduce the risk of fractures later in life May help reduce high blood pressure - Plays a role in relieving symptoms of PMS - Supports colon health - Good for adolescents and post-menopausal women - Aids function of nerves and muscles, including regulation of normal heart rhythm - Maintains steady metabolism - Conducts nerve impulses	**Contraindication:** Calcium, vitamin D and/or magnesium can interfere with tetracycline antibiotics, anticoagulants, and calcium channel blockers. Consult your physician before use if you are taking any thiazide diuretics, as these can cause extremely high (potentially toxic) levels of calcium in the body. Magnesium can increase levels of diuretics in the body. **Side Effects:** Calcium carbonate may cause symptoms of gas, bloating, or constipation. Excess calcium can contribute to the development of kidney stones, and may cause calcium deposits in the body.If anyone experience abdominal pain, appetite loss, diarrhea, irregular heartbeat, mood or mental changes, nausea, extreme fatigue, weakness or vomiting, discontinue use and contact a physician.	New		c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj |
		b)	Paracetamol 500 mg + Pamabrom 25 mg Tablet Paracetamol BP 500 mg + Pamabrom USP 25 mg	Acetaminophen and pamabrom combination can be used for conditions associated with pre-menstrual and menstrual periods: • Period pain • Bloatedness • Water weight gain • Discomforts	**Contraindications:** Paracetamol + Pamabrom is contraindicated who have known hypersensitivity to Paracetamol, Pamabrom or any other components of this product. **Side Effects:** Hives, difficulty in breathing, swelling of your face, lips, toungue or throat.	New		c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj |
11	RAK Pharmaceuticals Pvt. Ltd., Sreepur, Gazipur, Dhaka	a)	Ledipasvir 90 mg + Sofosbuvir 400 mg Tablet Ledipasvir INN 90 mg + Sofosbuvir INN 400 mg **Antiviral**	It is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults	**Contraindication:** None Side-effects: The most common adverse reactions (incidence greater than or equal to 10%, all grades) observed with treatment with this for 8, 12, or 24 weeks are fatigue and headache.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †Rvbv‡iK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	RAK Pharmaceuticals Pvt. Ltd., Sreepur, Gazipur, Dhaka	b) Daclatasvir 60 mg Film Coated Tablet Daclatasvir Dihydrochloride In House 66.0mg eq. to 60 mg Daclatasvir **Antiviral**	It is indicated in combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults	**Contraindications:** Coadministration with medicinal products that strongly induce cytochrome P450 3A4 (CYP3A4) and P-glycoprotein transporter (P-gp) and thus may lead to lower exposure and loss of efficacy of Daclatasvir. These active substances include but are not limited to phenytoin, carbamazepine, oxcarbazepine, phenobarbital, rifampicin, rifabutin, rifapentine, systemic dexamethasone, and the herbal product St John's wort (Hypericum perforatum). Side-effects: The most frequently reported adverse reactions were fatigue, headache, pruritus, insomnia, influenzalike, illness, dry skin, nausea, decreased appetite, alopecia, rash, asthenia, irritability, myalgia, anaemia, pyrexia, cough, dyspnoea, neutropenia, diarrhoea and arthralgia	New	EMA	Abyjvg`b Kiv †h‡Z cv‡i	Abyjvg`b Kiv nj
12.	ACI Ltd.	a) Linagliptin 7.5mg Tablet Linagliptin INN 7.5 mg **Antidiabetic**	Linagliptin indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	**Contraindications:** History of hypersensitivity reaction to linagliptin, such as urticaria, angioedema, or bronchial hyperreactivity **Side effects:** Normally nasopharyngitis, diarrhea, cough. Other adverse reactions reported in clinical studies were hypersensitivity (e.g., urticaria, angioedema, localized skin exfoliation, or bronchial hyperreactivity), and myalgia.	5mg Tablet		c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyi Kiv nj
		b) Linagliptin 5mg + Metformin 500mg Tablet Linagliptin INN 5mg + Metformin HCl BP 500mg **Antidiabetic**	The combination is indicated as an adjunct to diet and exercise to improve glycaemic control in adult patients inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of linagliptin and metformin. It is indicated in combination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea. It is also indicated in combination with insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in adult patients when insulin and metformin alone do not provide adequate glycaemic control.	**Contraindications:** Hypersensitivity to the active substances or to any of the excipients, Diabetic ketoacidosis, diabetic pre-coma. Renal failure or renal dysfunction (creatinine clearance < 60 ml/min). Acute conditions with the potential to alter renal function such as: dehydration, severe infection, shock, Acute or chronic disease which may cause tissue hypoxia such as: cardiac or respiratory failure, recent myocardial infarction, shock, Hepatic impairment, acute alcohol intoxication, alcoholism. **Side effects:** Gastrointestinal disorders such as, nausea, vomiting, diarrhea and decreased appetite and abdominal pain occur most frequently. Hypoglycaemia may occur when the combination is administered together with sulphonylurea.			c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	ACI Ltd.	c) Linagliptin 5mg + Metformin 1000mg Tablet Linagliptin INN 5mg + Metformin HCl BP 1000mg **Antidiabetic**	The combination is indicated as an adjunct to diet and exercise to improve glycaemic control in adult patients inadequately controlled on their maximal tolerated dose of metformin alone, or those already being treated with the combination of linagliptin and metformin. It is indicated incombination with a sulphonylurea (i.e. triple combination therapy) as an adjunct to diet and exercise in adult patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea. It is also indicated in combination with insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in adult patients when insulin and metformin alone do not provide adequate glycaemic control.	**Contraindications:** Hypersensitivity to the active substances or to any of the excipients, diabetic ketoacidosis, diabetic pre-coma. Renal failure or renal dysfunction (creatinine clearance < 60 ml/min) was found. Acute conditions with the potential to alter renal function such as: dehydration, severe infection, shock, also seen. Acute or chronic disease which may cause tissue hypoxia such as: cardiac or respiratory failure, recent myocardial infarction, shock, Hepatic impairment and acute alcohol intoxication, alcoholism. **Side effects:** Gastrointestinal disorders such as, nausea, vomiting, diarrhea and decreased appetite and abdominal pain occur most frequently. Hypoglycaemia may occur when the combination is administered together with sulphonylurea.			c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj |
		d) Human Albumin 5% Human Albumin 5% (50g/L)	Restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate. The choice of albumin rather than artificial colloid will depend on the clinical situation of the individual patient.	**Contraindications:** Hypersensitivity to albumin preparations or to any of the excipients. Albumin should be used with caution in conditions where hypervolemia and its consequences or hemodilution could represent a special risk for the patient. Examples of such conditions are: decompensated cardiac insufficiency, hypertension, Esophageal varices, cardiac failure, pulmonary edema, hemorrhagic diathesis, severe anemia, renal and post-renal anuria. **Side effects:** Hypersensitivity reactions (including anaphylaxis) with nausea, vomiting, increased salivation, fever, tachycardia, and hypotension and chills reported.		USFDA	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	ACI Ltd.	e) Paliperidone 3mg Extended Release tablet Paliperidone INN 3mg **Antipsychotic**	It is an atypical antipsychotic agent indicated for Treatment of schizophrenia Adults: Efficacy was established in three 6-week trials and one maintenance trial. Adolescents (ages 12-17): Efficacy was established in one 6-week trial. Treatment of schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers and/or antidepressants. Efficacy was established in two 6-week trials in adult patients.	**Contraindications:** Patients with known hypersensitivity to Paliperidone, risperidone & it excipients. **Side effects:** Commonly observed adverse reactions (incidence 5% and at least twice that for placebo) were Adults with schizophrenia: extrapyramidal symptoms, tachycardia, and akathisia. Adolescents with schizophrenia: somnolence, akathisia, tremor, dystonia, cogwheel rigidity, anxiety, weight increased, and tachycardia. Adults with schizoaffective disorder: extrapyramidal symptoms, somnolence, dyspepsia, constipation, weight increased, and nasopharyngitis.		USFDA BNF 69 (page no:244) (Modified Release)	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |
		f) Paliperidone INN 6mg Extended Release Tablet Paliperidone INN 6mg **Antipsychotic**	Do	Do		USFDA BNF 69 (page no:244) (Modified Release)	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |
		g) Paliperidone 9mg Extended Release Tablet Paliperidone INN 9mg **Antipsychotic**	Do	Do		USFDA BNF 69 (page no:244)	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |
13.	NIPRO JMI Pharma Ltd.	a) Erdosteine 300 mg Tablet Erdosteine INN 300 mg **Mucolytic Agents**	It is indicated for the symptomatic treatment of acute exacerbations of chronic bronchitis.	**Contraindications:** Erdosteine is contraindicated in patients • suffer from severe liver failure • suffer from severe decreased kidney function • having stomach ulcer • hypersensitivity to the active substance **Side effects:** Common: More than 1 in 100 people who take Erdosteine stomach pain, Uncommon: More than 1 in 1000 people who take Erdosteine, angioedema, breathing difficulties, diarrhea, eczema, headaches, nausea, redness of the skin, skin hypersensitivity reactions, taste changes, vomiting	New	BNF 68	c‡qvRb ‡bB wewfbœ Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wewfbœ Av‡e`b bvgÄyi Kiv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvwbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	NIPRO JMI Pharma Ltd.	b) Lactase 3000 Unit Tablet Lactase USP 100 mg Eq. to 3000 Units of Lactase **Enzyme**	Lactase is an enzyme that aids in the digestion of lactose.	**Contraindications:** Lactase is not recommended for use in children younger than 4 years of age. **Side effects:** No common side effects have been reported with lactase chewable tablets. Severe allergic reactions (rash; hives; difficulty breathing; tightness in the chest, swelling of the mouth, face, lips, or tongue) may seek medical attention.	New		c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyi Kiv nj
14	Delta Pharma Ltd., Kishoregonj	a) Suvorexant 10mg Tablet Suvorexant INN 10 mg **Orexin receptor antagonist**	Suvorexant is an orexin receptor antagonist indicated for the treatment of insomnia, characterized by difficulties with sleep onset and/or sleep maintenance	**Contra-indication:** Do not use in patients with narcolepsy **Side-effect:** The most common adverse reaction (reported in 5% or more of patients treated with BELSOMRA and at least twice the placebo rate) with Suvorexant was somnolence	New	USFDA	Abyjvg`b Kiv †h‡Z cv‡i	Abyjvg`b Kiv nj
15	Incepta Pharmaceuticals Ltd.	a) Daclatasvir 60 mg Tablet Daclatasvir Dihydrochloride In House 65.9203mg eq. to 60mg Daclatasvir **Antiviral**	It is indicated in combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults	**Contraindications:** Coadministration with medicinal products that strongly induce cytochrome P450 3A4 (CYP3A4) and P-glycoprotein transporter (P-gp) and thus may lead to lower exposure and loss of efficacy of Daclatasvir. These active substances include but are not limited to phenytoin, carbamazepine, oxcarbazepine, phenobarbital, rifampicin, rifabutin, rifapentine, systemic dexamethasone, and the herbal product St John's wort (Hypericum perforatum). Side-effects: The most frequently reported adverse reactions were fatigue, headache, pruritus, insomnia, influenzalike, illness, dry skin, nausea, decreased appetite, alopecia, rash, asthenia, irritability, myalgia, anaemia, pyrexia, cough, dyspnoea, neutropenia, diarrhoea and arthralgia	New	EMA	Abyjvg`b Kiv †h‡Z cv‡i	Abyjvg`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvMvwiK bvg		wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
16	Orion Pharma Ltd.	a)	Paracetamol 500 mg + Codeine Phosphate 15 mg Tablet Paracetamol BP 500 mg + Codeine Phosphate BP 15 mg **Analgesics**	For the relief of moderate pain. Codeine is indicated in patients older than 12 years of age for the treatment of acute moderate pain which is not considered to be relieved by other analgesics.	**Contraindications:** Hypersensitivity to either paracetamol or codeine, or any of the excipients of this tablet. Children under 12 years of age. This preparation is contraindicated. It is contraindicated in patients for whom opiate medications should not be used, such as patients with acute asthma, obstructive airway disease, respiratory depression, acute alcoholism, head injuries, raised intracranial pressure, after biliary surgery, patients suffering from diarrhea of any cause, and patients who have taken MAOIs within 14 days. **Side effects:** The commonest side effects of codeine are nausea, vomiting, light headedness, dizziness, sedation, shortness of breath and constipation. Euphoria, dysphoria, constipation, abdominal pain, and pruritus can occur as reactions to this product. Liver damage in association with therapeutic use of paracetamol has been documented; most cases have occurred in conjunction with chronic alcohol abuse. Regular prolonged use of codeine is known to lead to addiction and symptoms of restlessness			c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv nj
		b)	Paracetamol 500 mg + Sodium 173 mg Tablet Paracetamol BP 500 mg + Sodium Carbonate BP 631.83mg eq. to Sodium 173mg **Analgesics + Antipyretic**	This is a mild analgesic and antipyretic, and is recommended for the treatment of most painful and febrile conditions, for example, headache including migraine and tension headaches, toothache, backache, rheumatic and muscle pains, dysmenorrhoea, sore throat, and for relieving the fever, aches and pains of colds and flu.	**Contraindications:** Hypersensitivity to paracetamol or any of the other constituents. **Side effect:** Adverse events of paracetamol from historical clinical trial data are both infrequent and from small patient exposure. Due to limited clinical trial data, the frequency of these adverse events is not known but post-marketing experience indicates that adverse reactions to paracetamol are rare and serious reactions are very rare.			c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvwbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Orion Pharma Ltd.	c) Paracetamol 500 mg + Pseudoephedrine HCl 30 mg Tablet Paracetamol BP 500 mg + Pseudoephedrine HCl BP 30mg **Analgesics+ Antihistamine**	This tablet is indicated in adults and adolescents aged 12 to 18 years. Symptomatic relief of nasal congestion when combined with fever and/or pain such as, sore throat, sinus pain or headache in the common cold or influenza.	**Contraindications:** Hypersensitivity to paracetamol, pseudoephedrine, sympathomimetics or to any of the excipients. The antibiotics furazolidone and linezolid should not be taken. Not to be used by patients with the following conditions: Hypertension, Cardiovascular disease, Hyperthyroidism, Prostatic hypertrophy, Glaucoma & Severe renal impairment. Not to be used by patients taking beta-blockers. Not to be used in children under 12 years of age. **Side effect:** Blood dyscrasia, including thrombocytopenia and agranulocytosis are very rare. Hypersensitivity is rare. Psychiatric disorders: Nervousness, insomnia are common. Agitation, restlessness are uncommon. Hallucinations are rare. Nervous Dizziness are common. Dry mouth, nausea, vomiting are common. Skin and subcutaneous disorders: Rash, allergic dermatitis are rare. Urinary retention are uncommon. Minor tachycardia are uncommon. Cardiac arrhythmias are rare. Hepatic dysfunction is very rare.			c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv nj
	Orion Pharma Ltd.	d) Paracetamol 500 mg + Chlorpheniramine Maleate 2mg + Psedoephedrine HCl 30 mg Tablet Paracetamol BP 500 mg + Chlorpheniramine Maleate USP 2 mg + Psedoephedrine HCl BP 30 mg **Analgesics + Antihistamine**	Tablet can be used for: Blocked and runny nose, Headache and body ache & Fever.	**Contraindications:** Hypersensitivity to paracetamol, Chlorpheniramine or Pseudoephedrine or other constituents. **Side effect:** Blood dyscrasia, including thrombocytopenia and agranulocytosis are very rare. Hypersensitivity is rare. Psychiatric disorders: Nervousness, insomnia are common. Agitation, restlessness are uncommon. Hallucinations are rare. Dizziness are common. Gastrointestinal disorders: Dry mouth, nausea, vomiting are common. Rash, allergic dermatitis are rare. Urinary retention are uncommon. Cardiac disorders: Minor tachycardia are uncommon. Cardiac arrhythmias are rare. Hypertension are rare. Hepatobiliary disorders: Hepatic dysfunction is very rare.			c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg		wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Orion Pharma Ltd.	e)	Paracetamol 500 mg + Guaifenesin 100 mg + Pheylephrine 5 mg Tablet Paracetamol BP 500 mg + Guaifenesin BP 100 mg + Pheylephrine HCl BP 6.1mg eq. to Phenylephrine 5 mg **Analgesics + Antihistamine**	Tablet can be used for: Chesty cough, Blocked and runny nose, Sore throat, Headache and body ache & Fever.	**Contraindications:** Hypersensitivity to any of the ingredients. Antihistamines are contraindicated in patients receiving antihypertensive or antidepressant drugs containing monoamine oxidase (MAO) inhibitors since these agents may prolong and intensify anticholinergic and CNS depressant effects of antihistamines. **Side effect:** Guaifenesin is well tolerated and has a wide margin of safety. Side effects have been generally mild and infrequent. Nausea and vomiting are the side effects that occur most commonly. Dizziness, headache, and rash (including urticaria) have been reported rarely. Drowsiness, lightheadedness, nausea, and dryness of mouth. Less frequently restlessness, nervousness, trembling, or weakness may occur. CNS depression, CNS stimulation, anticholinergic effects, flushing of the face and shortness of breath, troubled breathing.			c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv nj
17	Eskayef Bangladesh Limited	a)	Naphazoline HCl 0.025gm + Pheniramine Maleate 0.30gm/100ml Ophthalmic Solution Naphazoline Hydrochloride USP 0.025gm + Pheniramine Maleate USP 0.30gm/100ml **Antihistamine**	For the symptomatic treatment of allergic conjunctivitis	**Contraindications:** The use of this eye Drops is contraindicated in patients who are known to experience narrow-angle glaucoma or who have known hypersensitivities to one or more of the components of this preparation **Side effects:** Ocular discomfort	Naphazoline Nitrate 5mg + Zinc Sulphate20 mg/100 ml Eye Drops	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Eskayef Bangladesh Limited	b) Empagliflozin 10mg + Linagliptin 5mg FC Tablet Empagliflozin INN 10mg + Linagliptin INN 5mg **Antidiabetic**	It is a sodium-glucose co-transporter 2 (SGLT2) inhibitor and dipeptidyl peptidase-4 (DPP-4) inhibitor combination product indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both empagliflozin and linagliptin is appropriate. **Limitations of use:** Not for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis. Has not been studied in patients with a history of pancreatitis	**Contraindications:** ➢ Severe renal impairment, end-stage renal disease, or dialysis ➢ History of hypersensitivity reaction to linagliptin, such as anaphylaxis, angioedema, exfoliative skin conditions, urticaria, or bronchial hyperreactivity. ➢ History of serious hypersensitivity reaction to empagliflozin **Side effects:** The most common adverse reactions associated with GLYXAMBI (a 5% or greater incidence) were urinary tract infections, nasopharyngitis, and upper respiratory tract infections.	Linagliptin 5mg Tablet	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj |
		c) Prednisolone Acetate 0.20gm + Sulfacetamide Sodium 10gm/100ml Ophthalmic Suspension Prednisolone Acetate USP 0.20gm + Sulfacetamide Sodium USP 10gm/100ml **Glucocorticosteroid + Antibacterial**	Indicated for steroid-responsive inflammatory ocular conditions for which a corticosteroid is indicated and where superficial bacterial ocular infection or a risk of bacterial ocular infection exists.	**Contraindications:** Contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal diseases of ocular structures. **Side effects:** Allergic sensitizations, local irritation.	Prednisolone 1% Eye Drops	USFDA	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Eskayef Bangladesh Limited	d) Conjugated Estrogens 0.45mg + Bazedoxifene 20mg Tablet **Conjugated Estrogens USP 0.45mg + Bazedoxifene Acetate INN 22.552mg eq. to 20mg Bazedoxifene**	It is a combination of conjugated estrogens with an estrogen agonist/antagonist indicated for treatment of the following conditions in women with a uterus: • Treatment of moderate to severe vasomotor symptoms associated with menopause • Prevention of postmenopausal osteoporosis **Limitation of Use:** It should be used for the shortest duration consistent with treatment goals and risks for the individual woman	**Contraindications:** • Undiagnosed abnormal uterine bleeding • Known, suspected, or past history of breast cancer • Known or suspected estrogen-dependent neoplasia • Active deep venous thrombosis, pulmonary embolism, or history of these conditions • Active arterial thromboembolic disease (for example, stroke, myocardial infarction) or history of these conditions • Hypersensitivity (for example, anaphylaxis, angioedema) to estrogens, Bazedoxifene, or any ingredients • Known hepatic impairment or disease • Known protein C, protein S, or antithrombin deficiency or other known thrombophilic disorders • Pregnancy, women who may become pregnant, and nursing mothers **Side effects:** In four prospective, randomized, placebo-controlled trials the common adverse reactions (incidence ≥ 5%) were muscle spasms, nausea, diarrhea, dyspepsia, abdominal pain upper, oropharyngeal pain, dizziness, and neck pain.	Conjugated Oestrogens 625mcg Tablet Conjugated Oestrogens 625mcg + Norgestrel 150mcg Tablet	USFDA	Family Planning Department-Gi gZvg‡Zi wfwË‡Z Abyôv`b Kiv †h‡Z cv‡i|	Family Planning Department-Gi gZvg‡Zi wfwË‡Z Abyôv`b Kiv nj|

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †Rvbv‡iK bvg		wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Eskayef Bangladesh Limited	e)	Tedizolid Phosphate 200mg/Vial IV injection Tedizolid Phosphate for Injection 310mg containing 200mg Tedizolid Phosphate/Vial **Antibiotic**	Tedizolid is an oxazolidinone-class antibacterial drug indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria. To reduce the development of drug-resistant bacteria and maintain the effectiveness of Tedizolid and other antibacterial drugs. Tedizolid should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.	**Contraindications:** None **Side Effects:** The most common adverse reactions (>2%) are nausea, headache, diarrhea, vomiting, and dizziness.	New	USFDA	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
		f)	Emedastine 0.050gm/100ml Ophthalmic Solution Emedastine Difumarate USP 0.088gm eq. to 0.050gm Emedastine/100ml **Ophthalmic Antihistamine**	Emedastine 0.05% ophthalmic solution is indicated for the temporary relief of the signs and symptoms of allergic conjunctivitis.	**Contraindications:** It is contraindicated in persons with a known hypersensitivity to emedastine difumarate or any of its components. **Side effects:** The most frequent adverse reaction was headache. The following adverse experiences were reported in less than 5% of patients: Abnormal dreams, asthenia, bad taste, blurred vision, burning or stinging, corneal infiltrates, corneal staining, dermatitis, discomfort, dry eye, foreign body sensation, hyperemia, keratitis, pruritus, rhinitis, sinusitis, and tearing. Some of these events were similar to the underlying disease being studied.	New	USFDA	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
		g)	Azelastine Hydrochloride 0.050gm/100ml Opthalmic Drop/Solution Azelastine Hydrochloride 0.050gm/100ml **Antihistamine**	It is indicated for the treatment of itching of the eye associated with allergic conjunctivitis.	**Contraindications:** It is contraindicated in persons with known or suspected hypersensitivity to any of its components. **Side effects:** The most frequently reported adverse reactions were transient eye burning/stinging (approximately 30%), headaches (approximately 15%) and bitter taste (approximately 10%). The occurrence of these events was generally mild.	New	USFDA	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Eskayef Bangladesh Limited	h) Iodoxamide 0.1gm/100ml Ophthalmic solution IodoxamideTromethamine INN 0.178gm eq. to 0.1gmIodoxamide/100ml **Antiallergic**	Treatment of the ocular signs and symptoms associated with vernal keratoconjunctivitis, giant papillary conjunctivitis, and allergic/atopic conjunctivitis.	**Contraindications:** Hypersensitivity to any component of this product. **Side effects:** Transient discomfort, Burning, Stinging, Itching or tearing	New		c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv nj
		i) Finafloxacin 0.3gm/100ml Otic Suspension Finafloxacin INN 0.3gm/100ml Otic Suspension **Antibiotic**	finafloxacin otic suspension 0.3% is indicated for the treatment of acute otitis externa (AOE) with or without an otowick, caused by susceptible strains of Pseudomonas aeruginosa and Staphylococcus aureus in patients age 1 year and older.	**Contraindications:** None **Side Effects:** Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice. A total of 618 patients were treated with FINAFLOXACIN in two Phase 3 clinical trials. The most frequently reported adverse reactions of those exposed to FINAFLOXACIN occurring at an incidence of 1% included ear pruritus and nausea.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		j) Sodium Fusidate 250mg FC Tablet Sodium Fusidate BP 250mg **Antibiotic**	Treatment of localized, as well as generalized, staphylococcal infections caused by susceptible organisms. In severe infections, deep-seated infections, infections due to methicillin-resistant Staphylococci or when prolonged therapy may be required, Sodium Fusidate must be given concurrently with other anti-staphylococcal antibiotic therapy.	**Contraindications :** • Concomitant treatment with statins • Hypersensitivity to fusidic acid or its salts **Side Effect:** Nausea & Vomiting, Diarrhoea, Abdominal pain, Dyspepsia, Abdominal discomfort			c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv nj
		k) Elemental Zinc 25mg Tablet Zinc Picolinate INN 118.364mg eq. to Elemental Zinc 25mg	Oral zinc therapy is indicated in zinc deficiency and/or zinc loosing conditions. Zinc deficiency can occur as a result of inadequate diet or malabsorption, excessive loss of zinc can occur in trauma, burns, diarrhoea and protein losing conditions. A zinc supplement is given until clinical improvement occurs but it may need to be continued in severe malabsorption, metabolic disease or in zinc-losing states.	**Contraindications:** It is contraindicated in those who are hypersensitive to any component of a zinc-containing supplement. **ADR/Side effects:** Zinc may cause nausea, vomiting, diarrhoea, stomach upset, heartburn, gastritis etc.	10mg Tablet		c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg		wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Eskayef Bangladesh Limited	l)	Rivaroxaban INN 2.5mg FC Tablet Rivaroxaban INN 2.5mg **Anticoagulant**	Reduction of Risk of Stroke and Systemic Embolism in Nonvalvular Atrial Fibrillation Prophylaxis of Deep Vein Thrombosis	**Contraindication:** • Active pathological bleeding • Severe hypersensitivity reaction **ADR/Side effects:** Hemorrhage, Wound secretion, Pain in extremity, Pruritus	10mg, 15mg & 20mg Tablet	BNF-69 Page No. 158	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj	
		m)	Phentermine 3.75mg+ Topiramate 23mg Extended-Release Capsule Phentermine HCl USP 4.666mg eq. to 3.75 mg Phentermine + Topiramate USP 23mg **Anorectic Agent**	It is a combination of phentermine, a sympathomimetic amine anorectic, and topiramate , an antiepileptic drug, indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of: 30 kg/m2 or greater (obese)) or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbidity such as hypertension, type 2 diabetes mellitus, or dyslipidemia **Limitations of Use:** The effect of the drug on cardiovascular morbidity and mortality has not been established. The safety and effectiveness of the drug in combination with other products intended for weight loss, including prescription and over-the-counter drugs, and herbal preparations, have not been established	**Contraindications:** Pregnancy Glaucoma, Hyperthyroidism During or within 14 days of taking monoamine oxidase inhibitors. **Side effects:** Most common adverse reactions are: paraesthesia, dizziness, dysgeusia, insomnia, constipation, and dry mouth	Topiramate 25mg/50mg/100mg Tablet	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj	
		n)	Phentermine 7.5mg+ Topiramate 46mg Extended-Release Capsule Phentermine HCl USP 9.332mg eq. to 7.5mg Phentermine + Topiramate USP 46mg **Anorectic Agent**	Do	Do	Topiramate 25mg/50mg/100mg Tablet	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj	

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Eskayef Bangladesh Limited	o) Phentermine 11.25mg+ Topiramate 69mg Extended-Release Capsule Phentermine HCl USP 13.999mg eq. to 11.25mg Phentermine + Topiramate USP 69.00mg **Anorectic Agent**	Do	Do	Topiramate 25mg/50mg/100mg Tablet	USFDA	c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv nj
		p) Phentermine 15mg+ Topiramate 92mg Extended-Release Capsule Phentermine HCl USP 18.665mg eq. to 15.0mg Phentermine + Topiramate USP 92.0mg **Anorectic Agent**	Do	Do	Topiramate 25mg/50mg/100mg Tablet		c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv nj
		q) Guaifenesin 2.0gm + Bromohexine HCl 0.080gm/100ml Syrup Guaifenesin USP 2.0gm + Bromohexine HCl BP 0.080gm/100ml **Mucolytic Agent**	It is indicated for the symptomatic relief of chesty or excessive mucus or productive cough in the following conditions: • Tracheobronchitis • Bronchitis with emphysema • Bronchiectasis • Bronchitis with bronchospasm • Chronic inflammatory pulmonary condition • Pneumonia	**Contraindications**: Patients with known hypersensitivity to any of its ingredients. It is contraindicated in patients with sever hypertension and severe coronary artery disease. **Side effects:** Gastrointestinal side effects may occur occasionally with Bromohexine and transient rise in serum aminotransferase values has been reported.	New		c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv nj
		r) Elemental Zinc 50mg capsule Zinc Picolinate INN 236.728mg eq. to 50mg elemental zinc	Oral zinc therapy is indicated in zinc deficiency and/or zinc loosing conditions. Zinc deficiency can occur as a result of inadequate diet or malabsorption, excessive loss of zinc can occur in trauma, burns, diarrhoea and protein losing conditions. A zinc supplement is given until clinical improvement occurs but it may need to be continued in severe malabsorption, metabolic disease or in zinc-losing states.	**Contraindications:** It is contraindicated in those who are hypersensitive to any component of a zinc-containing supplement. **Side Effect:** Zinc may cause nausea, vomiting, diarrhoea, stomach upset, heartburn, gastritis etc.	10mg Tablet		c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyÿ Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Eskayef Bangladesh Limited	s) Vorapaxar INN 2.08mg FC Tablet Vorapaxar Sulfate INN 2.50mg eq. to 2.08mg Vorapaxar **Thrombin recptor antagonist**	Vorapaxar is a protease-activated receptor-1 (PAR-1) antagonist, indicated for the reduction of thrombotic cardiovascular events in patients with a history of myocardial infarction (MI) or with peripheral arterial disease (PAD). Vorapaxar has been shown to reduce the rate of a combined endpoint of cardiovascular death, MI, stroke, and urgent coronary revascularization (UCR).	**Contraindication:** Like other antiplatelet agents, it increases the risk of bleeding. Avoid use with strong CYP3A Inhibitors or inducers. **Side Effect:** Bleeding, including life-threatening and fatal bleeding, is the most commonly reported adverse reaction.	New	USFDA	Abyôgv`b Kiv †h‡Z cv‡i |	Abyôgv`b Kiv nj |
		t) Carisoprodol BP 350mg tablet Carisoprodol BP 350mg tablet **Skeletal Muscle Relaxant**	Carisoprodol is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions.	**Contraindications:** Carisoprodol is contraindicated in patients with acute intermittent porphyria, and in patients who are allergic to or who have had idiosyncratic reactions to Carisoprodol or Meprobamate related compounds **Side Effect:** • Tachycardia, postural hypotension, and facial flushing • Drowsiness, dizziness, vertigo • Nausea, vomiting, hiccup, and epigastric distres	New	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyÿ Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyÿ Kiv nj |
		u) Carisoprodol BP 250mg tablet Carisoprodol BP 250mg tablet	**Do**	**Do**	New		Abyôgv`b Kiv †h‡Z cv‡i |	Abyôgv`b Kiv nj |
		v) Aliskiren INN 150mg + Amlodipine BP 10mg FC tablet Aliskiren Hemifumarate INN 165.778mg eq. Aliskiren 150mg + Amlodipine Besilate BP 13.868mg eq. to Amlodipine 10mg **Antihypertensive**	It is a combination of aliskiren, a renin inhibitor, and amlodipine, a dihydropyridine calcium channel blocker, indicated for the treatment of hypertension, to lower blood pressure: • As initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals. • In patients not adequately controlled with monotherapy. • As a substitute for its titrated components. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.	**Contraindications:** Do not use with angiotensin receptor blockers (ARBs) or angiotensinconverting enzyme inhibitors (ACEIs) in patients with diabetes. Known hypersensitivity to any of the components. **Side Effects:** The most common adverse event (incidence ≥2% and more common than with placebo) is peripheral edema.	New	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyÿ Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyÿ Kiv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †Rvbv‡iK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UK‡bK`vj mve-K‡g‡Ui 63 Zg mfvi wm×vš	mfvi wm×vš
	Eskayef Bangladesh Limited	w) Aliskiren 300mg + Amlodipine 5mg FC tablet Aliskiren Hemifumarate INN 331.556mg eq. Aliskiren 300mg + Amlodipine Besilate BP 6.934mg eq. to Amlodipine 5mg **Antihypertensive**	Do	Do			c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyÿ Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyÿ Kiv nj	
		x) Aliskiren 300mg + Amlodipine 10mg FC Tablet Aliskiren Hemifumarate INN 331.556mg eq. Aliskiren 300mg + Amlodipine Besilate BP 13.868mg eq. to Amlodipine 10mg **Antihypertensive**	Do	Do			c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyÿ Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyÿ Kiv nj	
		y) Suvorexant 5 mg Tablet Suvorexant In House 5 mg **Orexin receptor antagonist**	Suvorexant is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.	**Contraindications:** Suvorexant is contraindicated in patients with narcolepsy. **Side Effects:** The following serious adverse reactions are discussed in greater detail in other sections: CNS depressant effects and daytime impairment; abnormal thinking and behavioral changes; worsening of Depression/Suicidal ideation; Sleep paralysis, hypnagogic/hypnopompic hallucinations, cataplexy-like symptoms	New	USFDA	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyÿ Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyÿ Kiv nj
		z) Suvorexant 10 mg Tablet Suvorexant In house 10 mg **Orexin receptor antagonist**	Suvorexant is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.	Do	New	USFDA	Abyfgv`b Kiv †h‡Z cv‡i	Abyfgv`b Kiv nj
		aa) Suvorexant 15 mg Tablet Suvorexant In House 15mg **Orexin receptor antagonist**	Suvorexant is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.	Do	New	USFDA	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyÿ Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyÿ Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Eskayef Bangladesh Limited	ab) Suvorexant 20 mg Tablet Suvorexant In House 20mg **Orexin receptor antagonist**	Suvorexant is indicated for the treatment of insomnia characterized by difficulties with sleep onset and/or sleep maintenance.	DO	New	USFDA	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj
		ac) Bismuth Subsalicylate 3.50gm/100ml Suspension Bismuth Subsalicylate USP 3.50gm/100ml **Antacid**	• Heartburn • Upset Stomach • Indigestion • Nausea &Diarrhoea	**Contraindications:** Patients sensitive to salicylates including methyl salicylate(oil of wintergreen), or to other nonsteroidal anti-inflammatory drugs (NSAIDs), may be sensitive to bismuth subsalicylate also **Side Effects:** Fecal impaction in elderly patients	Bismuth Subcitrate 120mg Tablet Bismuth Subsalicylate 1.750gm/100ml Oral Suspension		c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj
		ad) Riociguat 0.5mg FC tablet Riociguat INN 0.5mg **Antihypertensive**	It is a soluble guanylate cyclase (sGC) stimulator indicated for the treatment of adults with: Persistent/recurrent Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class. Pulmonary Arterial Hypertension (PAH) (WHO Group 1) to improve exercise capacity, improve WHO functional class and to delay clinical worsening.	**Contraindications:** Pregnancy, Use with nitrates or nitric oxide donors in any form. Use with PDE inhibitors **Side Effects:** Adverse reactions occurring more frequently (≥3%) on Adempas compared to placebo are headache, dyspepsia/gastritis, dizziness, nausea, diarrhea, hypotension, vomiting, anemia, gastroesophageal reflux, and constipation.	New	USFDA	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj
		Ae) Naproxen Sodium 220mg + Pseudoephedrine HCl 120mg Extended Release Tablet Naproxen Sodium USP 220mg eq. to Naproxen 200mg + Pseudoephedrine HCl USP 120mg	Temporarily relieves these cold sinus and flue symptoms- sinus pressure, minor body aches and pains, Headache, Nasal and sinus congestion (promotes sinus drainage and restores freer breathing through the nose) Fever	**Contraindications:** • Contraindicated in patients with known hypersensitivity to any of its ingredients. • Children under 12 years of age. **Side Effects:** Asthma, diabetes, thyroid disease, trouble urinating due to an enlarged prostate gland.	Naproxen 250mg/500mg Tablet	USFDA	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvMvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Eskayef Bangladesh Limited	af) Lurasidone HCl 60mg FC Tablet LurasidoneHCl INN 60mg **Antipsychotic**	Lurasidone is indicated for the treatment of patients with schizophrenia.	**Contraindications:** • Contraindicated in any patient with a known hypersensitivity to Lurasidone or any components in the formulation. Angioedema has been observed with Lurasidone. • Lurasidone is contraindicated with strong CYP3A4 inhibitors (e.g., ketoconazole) and strong CYP3A4 inducers. **Side Effects:** Somnolence, Akathisia, Nausea, Parkinsonism, Agitation			c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj |
		ag) Dalbavancin 500mg/Vial Lyophilized Powder for Injection Dalbavancin HCl In-House 510.035mg eq. to 500mg Dalbavancin/Vial **Antibiotic**	Dalbvacin for injection is indicated for the treatment of adult patients with acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: Staphylococcus aureus (including methicillin-susceptible and methicillin-resistant strains), Streptococcus pyogenes, Streptococcus agalactiae and Streptococcus anginosus group(including S. anginosus, S. intermedius, S. constellatus)	**Contraindications:** Dalbvacin is contraindicated in patients with known hypersensitivity to dalbavancin. **Side Effects:** The most common adverse reactions in patients treated with Dalbavancin were nausea (5.5%), headache (4.7%), and diarrhea (4.4%).	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |
		ah) Azilsartan Medoxomil 80mg + Chlorthalidone 12.5mg FC Tablet Azilsartan Kamedoxomil INN 85.36mg eq. to 80mg Azilsartan Medoxomil + Chlorthalidone BP 12.5mg **Antihypertensive**	Azilsartanmedoxomil is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.	**Contraindications:** • Hypersensitivity to the active substance or to any of the excipients. • Second and third trimester of pregnancy **Side Effects:** Dizziness, Hypotension	Chlorthalidone 25mg & 50mg Tablet		c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbwiK bvg		wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Eskayef Bangladesh Limited	ai)	Ceftolozane INN 1.0 gm + Tazobactam INN 0.5gm/vial Sterilized Lyophilized Powder for injection Ceftolozane Sulphate INN 1.147gm eq. to Ceftolozane 1.gm + Tazobactam Sodium In House 0.537gm eq. to Tazobactam 0.5gm/Vial **Antibiotic**	It is a combination product consisting of a cephalosporin class antibacterial drug and a beta-lactamase inhibitor indicated for the treatment of the following infections caused by designated susceptible microorganisms: Complicated Intra-abdominal Infections, used in combination with metronidazole and Complicated Urinary Tract Infections, including Pyelonephritis	**Contraindications:** It is contraindicated in patients with known serious hypersensitivity to the components of (ceftolozane and tazobactam) piperacillin/tazobactam, or other members of the beta-lactam class**.** **Side Effects:** The most common adverse reactions (≥ 5% in either indication) are nausea, diarrhea, headache and pyrexia. .	New	**USFDA**	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		Aj)	Ceftazidime 2.0gm + Avibactam 0.50gm/Vial Sterilized Lyophilized Powder for injection Ceftazidime Pentahydrate USP 2.395mg eq. to 2.0gm Ceftazidime + Avibactam Sodium INN 0.551 gm eq. to 0.500gm Avibactam/Vial **Antibiotic**	For the treatment of patients 18 years or older with following infections caused by the susceptible microorganisms. 1. Complicated intra-abdominal infections (cIAI), used in combination with metronidazole. 2. Complicated Urinary Tract Infections (cUTI) including Pyelonephritis.	**Contraindications:** In patients with known hypersensitivity to the products, Ceftazidime or other Cephalosporin Class. **Side effects:** The reported side effects are vomiting, nausea, constipation and anxiety.	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
18.	Popular Pharmaceuticals Limited	a) Gatifloxacin 0.30gm + Loteprednol Etabonate INN 0.50gm/100ml Ophthalmic Suspension Gatifloxacin Sesquihydrate INN 0.322gm eq. to Gatifloxacin 0.30gm + Loteprednol Etabonate INN 0.50gm/100ml **Antibiotic**	It is indicated for the treatment of post operative inflammatory conditions of the eye.	Contraindications: Loteprednol and Gatifloxacin as with other ophthalmic conicosteraids. Is contraindicated in most viral diseases of the cornea and conjunctiva including epithelial herpes simpiex and also in mycobacterial infection of the eye and fungal diseases of ocular structures. It is also contraindicated in individuals with known or suspected hypersensitivity to any of the ingredients of this preparation and to alter corticosteroids. It Is also contraindicated In patients with a history, of Hypersensitivity to other quinlones, acetylsalicylic acid and other nonsteroidal inflammatory medicines Side effects: Adverse reactions have occurred with steroid/anti- infective combination drugs which can be attributed to the steroid component the anti-infective component, or the combination. Reactions associated with ophthalmic steroids include elevated IOP, which may be associated with infrequent optic nerve damage visual acuity and field detects posterior subcapsular cataract formation, delayed wound healing, and secondary ocular infections from pathogens including herpes simplex, and perforation of the globe where there is thinning of cornea or sclera. The most frequently reported adverse effects for gatifloxacin in the overall study population were conjunctival irritation. increased lacrimation, lieratitis and papillary conjunctivitis These events occurred in approximately 5-10% 01 (wells Other reported reactions occurring in 1-4% of patients were chemosis, conjunctival hemorrhage, dry eye, eye discharge, eye irritation, eye pain. eyelid edema, headache red eye reduced visual acuity and taste disturbance The adverse events with the fixed dose combination it a Allergen study were mild to moderate in severity. The adverse events reported were irritation, pain, redness, photophobia, stinging, itching, discharge and blurted vision. Redness was the most commonly observed adverse event occurring in 6%. Itching, discharge photophobia and blurred vision were seen In less than 2% cases.			Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †Rvwbwi‡K bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Popular Pharmaceuticals Limited	b) Azithromycin 500mg + Ambroxol Hydrochloride 75mg Extended Release Bi-Layer Film Coated Tablet Azithromycin USP 524mg eq. to Azithromycin 500mg + Ambroxol Hydrochloride BP 75mg **Antibiotic + Expectorant**	Azitromycin + Ambroxol is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below. • Upper Respiratory Tract Infections Pharyngitis/Tonsillitis Acute Bacterial Sinusitis, Otitis Media • Lower Respiratory Tract Infections, Acute Bacterial Exacerbations of Chronic Obstructive Pulmonary Disease Community-Acquired Pneumonia [CAP]	Contraindications: Azithromycin Plus is contraindicated in patients with known hypersensitivity to ambroxol, azithromycin, erythromycin, or any macrolide antibiotic. Side effects: In clinical trials, most of the reported side effects with azithromycin were mild to moderate in severity and were related to the gastrointestinal tract, e.g., nausea, vomiting, diarrhea, or abdominal pain. Rarely but potentially serious side effects were angioedema and cholestatic jaundice. Ambroxol: The side effects on account of ambroxol include gastrointestinal side effects, skin rashes, headache, dizziness and sweating			c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv nj
		c) Azithromycin 250mg + Ambroxol Hydrochloride BP 75mg Extended Release Bi-Layer Film Coated Tablet Azithromycin USP 262mg eq. to Azithromycin 250mg + Ambroxol Hydrochloride BP 75mg	Do	Do			c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv nj
		d) Multivitamin and Mineral Supplement Tablet Dry Vitamin A Acetate 500 BP 1.00mg eq. to Vitamin A 500IU + Ascorbic Acid (DC) BP 75mg + Dry Vitamin D3 100 BP 2mg eq. to Vitamin D 200IU + Dry Vitamin E Acetate 50% DC BP 50mg eq. to Vitamin E 25IU + Dry Vitamin K1 5% BP0.30mg eq. to Vitamin K 15mcg + Thiamin Nitrate (Vitamin B1) BP 1.86mg eq. to Thiamin	Multivitamins and minerals are used to provide substances that are not taken in through the diet. Multivitamins and minerals are also used to treat vitamin or mineral deficiencies caused by illness, pregnancy, poor nutrition, digestive disorders, certain medications, and many other conditions. ➢ An all-in-one eye vitamin and multivitamin / multimineral supplement ➢ Helps replenish vital nutrients that can protect eye health ➢ Provides the benefits of a	**Contraindications:** Multivitamin & Mineral Supplement is contraindicated in patients who are hypersensitivity to or any ingredient in the formulation. **Side effects:** When taken as directed, multivitamins and minerals are not expected to cause serious side effects. Common side effects may include: ▪ Upset stomach ▪ Headache ▪ Unusual or unpleasant taste in your mouth.			c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyK iv nj

		1.5mg + Riboflavin (Vitamin B2 BP 0.85mg + Niacin USP 10mg + Pyridoxine Hydrochloride (Vitamin B6) BP 1mg + Folic Acid BP 0.20mg + Cyanocobalamin (1%) (Vitamin B12) BP 0.30mg eq. to Vitamin B12 3mcg + Biotin 0.015mg + Calcium Pantothenate BP 4.663mg eq. to Pantothenic Acid 5mg + Calcium Carbonate (Heavy) BP 252.294mg eq. to Calcium 100mg + Anhydrous Calcium Hydrogen Phosphate BP 30.742mg eq. to Phosphorous 7mg + Potassium Iodide BP 0.098mg eq. to Iodine 75mcg + Magnesium Oxide (Heavy) BP 82.50mg eq. to Magnesium 50mg + Zinc Oxide BP 15.55mg eq. to Zinc 12.50mg + Copper Gluconate USP 27.00mg eq. to Copper 1mg + Manganese Sulphate Monohydrate BP 3.075mg eq. to Manganese 1mg + Chromic Chloride Hexahydrate USP 0.246mg eq. to Chromium 60mcg + Sodium Molybdate Dihydrate 1% 9.46mg eq. to Molybdenum 37.5mg + Lutein (5%) 100.00mg eq. to Lutein 5mg + Zeaxanthin (5%) 20.00mg eq. to Zeaxanthin 1mg + Lycopene (5%) 3.00mg eq. to Lycopene 150mcg	complete multivitamin					

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Popular Pharmaceuticals Limited	e) Olopatadine 0.70gm/100ml Ophthalmic Solution Olopatadine Hydrochloride USP 0.777gm eq. to Olopatadine 0.70gm/100ml **Antiallergic**	Olopatadine is indicated for the treatment of ocular itching associated with allergic conjunctivitis.	**Contraindications:** None **Side effects:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. These events were blurred vision, dry eye, superficial punctate keratitis, dysgeusia and abnormal sensation in eye.	1% and 0.2% Eye Drops 0.6% Nasal Spray	USFDA	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i |	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj |
19	IBN SINA Pharmaceutical Ind.Ltd., Gazipur	a) Ceftolozane 1gm + Tazobactam 0.5gm/Vial IV Injection Ceftolozane Sulfate INN 1.147gm eqv.to 1.0 gm Ceftolozane +Tazobactam Sodium USP 0.537gm eqv. to 0.5 gm Tazobactam/Vial **Antibiotic**	(Ceftolozane + Tazobactam) with metronidazole is indicated for use in complicated intra-abdominal infections cause by Enterobacter cloacae, Escherichia coli, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Pseudomonas aeruginosa, Bacteroides fragilis, Streptococcus anginosus, Streptococcus constellatus, and Streptococcus salivarius **Complicated urinary tract infections**: Indicated for complicated urinary tract infections, including pyelonephritis, caused by Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, and Pseudomonas aeruginosa	**Contraindication:** Contraindicated in patients with known serious hypersensitivity to Ceftolozane+Tazobactam, Piperacillin+Tazobactam, or other members of the beta-lactam class. **Adverse Effects:** The most common adverse reactions are nausea, diarrhea, headache and pyrexia (fever).	New	USFDA	Abyjgv`b Kiv †h‡Z cv‡i |	Abyjgv`b Kiv nj |

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	IBN SINA Pharmaceutical Ind.Ltd., Gazipur	b) Ledipasvir 90mg + Sofosbuvir 400mg Tablet Ledipasvir INN 90 mg + Sofosbuvir INN 400 mg **Antiviral**	The fixed dose combination Ledipasvir-Sofosbuvir (90 mg/400 mg) for the treatment of chronic hepatitis C genotype 1 in both treatment-naive and treatment-experienced patients. The treatment duration depends on prior treatment experience and the presence or absence of cirrhosis. Treatment experience is defined as patients who have failed treatment with either peginterferon plus ribavirin or peginterferon plus ribavirin plus a HCV protease inhibitor. *Genotype 1 treatment-naive patients with or without cirrhosis: 12 weeks. *Genotype 1 treatment-experienced patients without cirrhosis: 12 weeks. *Genotype 1 treatment-experienced patients with cirrhosis: 24 weeks. Treatment experience is defined as patients who have failed treatment with either peginterferon plus ribavirin or peginterferon plus ribavirin plus a HCV protease inhibitor.	**Contraindication:** Hypersensitivity to the active substances or to any of the excipients and Co-administration with rosuvastatin or St. John's wort **Side Effects:** Available data from clinical trials has demonstrated the combination of Ledipasvir and Sofosbuvir has been very well tolerated. The most common reported adverse effects are fatigue and headache.	Sofosbuvir 400 mg Tablet	USFDA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	Av‡e`bKvix c`Ë USFDA or MHRA Ref.	‡UKwbK¨vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	IBN SINA Pharmaceutical Ind.Ltd., Gazipur	c) Ranibizumab 6 mg/ml Ophthalmic Intravitreal Injection Ranibizumab INN 6 mg/ml **Opthalmological Agent**	**Ranibizumab is indicated for the treatment of patients with:** ➢ Neovascular (Wet) Age-Related Macular Degeneration (AMD). ➢ Macular Edema Following Retinal Vein Occlusion (RVO). ➢ Diabetic Macular Edema (DME). ➢ Diabetic Retinopathy (Non Proliferative Diabetic Retinopathy (NPDR), Proliferative Diabetic Retinopathy (PDR)) In patients With Diabetic Macular Edema (DME).	**Contraindication:** Ranibizumab is contraindicated in patients with ocular or periocular infections, known hypersensitivity to Ranibizumab or any of the excipients in Ranibizumab. Hypersensitivity reactions may manifest as severe intraocular inflammation. **Side-effects:** The following adverse reactions are discussed in greater detail in the ➢ Endophthalmitis and Retinal Detachments ➢ Increases in Intraocular Pressure ➢ Thromboembolic Events ➢ Fatal Events in patients with DME and DR at baseline	New	USFDA	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
		d) Ranibizumab 10 mg/ml Ophthalmic Intravitreal Injection Ranibizumab INN 10 mg/ml **Opthalmological Agent**	Ranibizumab is indicated for the treatment of patients with: ➢ Neovascular (Wet) Age-Related Macular Degeneration (AMD). ➢ Macular Edema Following Retinal Vein Occlusion (RVO). ➢ Diabetic Macular Edema (DME). ➢ Diabetic Retinopathy (Non Proliferative Diabetic Retinopathy (NPDR), Proliferative Diabetic Retinopathy (PDR)) In patients With Diabetic Macular Edema (DME).	**Contraindication:** Ranibizumab is contraindicated in patients with ocular or periocular infections, known hypersensitivity to Ranibizumab or any of the excipients in Ranibizumab. Hypersensitivity reactions may manifest as severe intraocular inflammation. **Side-effects:** The following adverse reactions are discussed in greater detail in the ➢ Endophthalmitis and Retinal Detachments ➢ Increases in Intraocular Pressure ➢ Thromboembolic Events Fatal Events in patients with DME and DR at baseline	New	USFDA	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj

2.3 Proposed Product for Locally Manufacture (Veterinary)

bs	c¯ZKvi‡Ki bvg	Jl‡ai bvg I †RvbviK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	‡UKwbK¨vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
01	Square Pharmaceuticals Ltd., Agrovet Division, Pabna	a) Enramycin Hydrochloride INN 8gm/100gm Powder (Vet) Enramycin Hydrochloride INN 8gm/100gm (For veterinary use only).	Necrotic enteritis, Streptococcosis and Staphylococcosis. Improves feed efficiency and acts as a growth promoter.	**Contra-indications:** Birds with a known hypersensitivity to Enramycin or any other component of the product should not be used. **Adverse effects:** No side effect is reported at the recommended dose.	New	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj
		b) Amprolium 10gm + Ethopabate 0.5gm + Sulfaquinoxaline 6gm + Menadione (Vitamin K_3) 0.2gm + Ascorbic Acid (Vitamin-C) 2gm/100gm Powder (Vet) Amprolium HCI BP (vet) 11.3gm (eq. to Amprolium 10gm) + Ethopabate BP (vet) 0.5gm + Sulfaquinoxaline Sodium INN 6.44gm (eq. to Sulfaquinoxaline 6gm) + Menadione Sodium Bisulphite INN 0.382gm [eq. to Menadione (Vitamin K_3) 0.2gm] + Ascorbic Acid (Vitamin-C) BP 2gm /100gm (For veterinary use only).	This is an anticoccidial drug for treatment and control of coccidiosis in poultry. This combination is developed to take the advantage of the synergistic benefits of the three chemicals against a mixed infection of *Eimeria acervulina, Eimeria maxima, Eimeria necatrix, Eimeria tenella, Eimeria brunette* at relatively safe levels of each drug by itself.	**Contra-indications:** Do not administer to animals with kidney dysfunctions. **Adverse effects:** No adverse effects on the growth of chicken, on feed efficiency or on egg production and hatchability.	New	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj
02	Acme Laboratories Ltd.	a) Liquid Paraffin 25.00 ml + Magnesium Hydroxide 6.00mg/100 ml Oral Emulsion, 500 ml Bottle Liquid Paraffin BP 25.00 ml + Light Magnesium Oxide BP 4.147 gm (Eqv. to 6.00 mg Magnesium Hydroxide)/100 ml Oral Emulsion, 500 ml Bottle (For veterinary use only).	Indicated for the treatment of constipation, bloat, acidosis, simple indigestion, impaction & abomasal ulceration.	**Contraindication:** In animal with dehydration and renal failure. **Side effects:** Diarrhoea may occur.	New	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	Jl‡ai bvg I †RvbvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	‡UKwbK¨vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Acme Laboratories Ltd.	b) Dried Aluminium Hydroxide 3.216 gm + Aluminium Hydroxide Gel 17.50 gm + Magnesium Hydroxide 8.00gm + Simethicone 0.600 gm)/100 ml Oral Suspension Dried Aluminium Hydroxide BP 3.216 gm + Aluminium Hydroxide Gel USP 17.50 gm + Magnesium Hydroxide BP 8.00 gm + Simethicone Emulsion USP 2.00 gm Eq. to Simethicone 0.600 gm/100 ml (For veterinary use only).	Indicated for the treatment of bloat, acidosis, simple indigestion, impaction, constipation & abomasal ulceration.	**Contraindication:** In animal with dehydration and renal failure. **Side effects:** Diarrhoea & constipation may occur.	New	Abyôgv`b Kiv †h‡Z cv‡i|	Abyôgv`b Kiv nj|
		c) Paracetamol 50 gm/100gm Water Soluble Powder Paracetamol BP 50 gm/100gm Water Soluble Powder (For veterinary use only).	Fever & pain of poultry & livestock.	**Contraindication:** The drug is contraindicated where there is possibility of gastro-intestinal ulceration or bleeding and animals hypersensitive to Paracetamol. **Side effects:** Occasional constipation may occur.	New	c‡qvRb ‡bB wewfbœ Avw‡e`b bvgÄyi Kiv †h‡Z cv‡i|	c¥we‡ePbvi Rb¨ cieZx †UKwbK¨vj mve-KwgwUi mfvq Dc¯'vcb Kiv n‡e|
		d) Metronidazole 30gm/100gm Water Soluble Powder Metronidazole BP 30gm/100gm Water Soluble Powder (For veterinary use only).	Poultry : Histomoniasis, Trichomoniasis etc. Livestock : Metritis, pyometra, retained placenta, vaginitis, gingivitis, calf scour, balantidiasis, trichomoniasis, giardiasis etc.	**Contraindication:** Animals hypersensitive to Metronidazole or any other ingredient of the product. **Side effects:** Reversible neurological depression, ataxiaand hepatic impairment may occur.	New	Abyôgv`b Kiv †h‡Z cv‡i|	Abyôgv`b Kiv nj|
		e) Doxycycline Hyclate 20gm + Tylosin Tartrate 10 gm + Bromhexine Hydrochloride 2gm/100gm Water Soluble Powder Doxycycline Hyclate BP 20gm + Tylosin Tartrate BP 10 gm + Bromhexine Hydrochloride BP 2gm/100gm (For veterinary use only).	For the prevention and treatment of respiratory & gastrointestinal tract infections of Large Animal & Poultry caused by- Mycoplasma, Pasteurella, *E.coli*, Streptococcus, Hemophilus, Rickettsia, Campylobacter, *Staphylcoccus ect.,* Bordetella, Salmonella, Chlamydia.	**Contraindication:** Animal hypersensitive to any of the ingredients. Concurrent administration of Penicillins, Cephalosporines & Quinolones is contraindicated. **Side effects:** Diarrhoea may occur in some cases. Discoloration of teeth in young animals.	New	Abyôgv`b Kiv †h‡Z cv‡i|	Abyôgv`b Kiv nj|

bs	c¯ZKvi‡Ki bvg	Jl‡ai bvg I †RvlbvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	‡UKwbK¨vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Acme Laboratories Ltd.	f) Meloxicam 100 mg + Paracetamol 1500 mg Bolus Meloxicam BP 100 mg + Paracetamol BP 1500 mg (For Veterinary Use Only)	Treatment of pneumonia, broncho pneumonia, arthritis,otitits, pyrexia of unknown origin, pain and fever associated with inflammation.	**Contraindication:** Contraindicated in animals with known hypersensitivity to Meloxicam, Paracetamol or any other ingredients of the product. It is also contraindicated in animals less than six weeks old, animals with impaired renal, hepatic or cardiac function. **Side effects:** Usually well tolerated at recommended doses. Prolong use may cause gastrointestinal lesions, inappetance, vomiting and diarrhoea.	New	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i|	c¥he‡ePbvi Rb¨ cieZx †UKwbK¨vj mve-KwgwUi mfvq Dc¯'vcb Kiv n‡e|
		g) Ceftriaxone for Injection 0.500gm/vial Injection Ceftriaxone Sodium Sterile Powder USP 0.595 g (Equivalent to 0.500 g of Ceftriaxone)/Vial (For Veterinary Use Only)	Ceftriaxone Injection is indicated for the treatment of wide variety of infections caused by sensitive gram-positive, gram-negative and anaerobic organisms. This drug has high potential application in- 1. Respiratory tract infections (Broncho-pneumonia, Pneumonia). 2. Gastrointestinal infections (Calf scour, enteritis, diarrhea). 3. Uro-genital tract infections (Metritis, Nephritis, Pyometra, Cystitis). 4. Skin and soft tissue infections (external wound, abscesses etc.). 5. Bone and joint infections (Arthritis). 6. Otitis (media, externa, interna).	**Contraindication:** Contraindicated to animals with known hypersensitivity to cephalosporin class of antibiotics. **Side effects:** Hypersensitive reactions (acute anaphylaxis or angioedema, allergic agranulocytosis, fever, serum sickness, urticaria, diarrhoea, thrombocytosis etc.).		Abyjgv`b Kiv †h‡Z cv‡i|	Abyjgv`b Kiv nj|
		h) Diphenhydramine Hydrochloride 500 mg Bolus Diphenhydramine Hydrochloride BP 500 mg (For Veterinary Use Only)	It is indicated for allergy of diverse origins such as cutaneous allergies, urticaria, angioneurotic edema, relief of coughing, laminitis, anaphylactic shock, allergic reactions to the medicaments, eczema, pruritis, photosensitization, insect bites etc.	**Contraindication:** Animals those are hypersensitive to Diphenhydramine Hydrochloride or any other antihistamine. **Side effects:** CNS depression (drowsiness), anti-cholinergic (dry mouth, urinary retention), diarrhoea etc. may occur in some cases.	New	Abyjgv`b Kiv †h‡Z cv‡i|	Abyjgv`b Kiv nj|

bs	c¯ZKvi‡Ki bvg	Jl‡ai bvg I †RvbvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	‡UKwbK¨vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Acme Laboratories Ltd.	i) Calcium, Magnesium, Phosphorus, Vitamin B_{12} & Vitamin D_3 Oral Solution Cyanocobalamin (Vitamin B_{12}) 0.1% BP 0.100 g (Eqv. to 100 mcg Vitamin B_{12}) + Vitamin D_3 (1.0 MIU/g) BP 0.008 g (Eqv. to 8000 IU Vitamin D_3) + Calcium Carbonate (Ca = 40.04%) BP 1.356 g (Eqv. to 542.9 mg Calcium) + Dibasic Calcium Phosphate Dihydrate (Ca = 23.28% & P = 17.99%) BP 4.661 g (Eqv. to 1085.1 mg Calcium & 838.5 mg Phosphorous) + Heavy Magnesium Oxide (Mg = 60.31%) BP 0.1659 g (Eqv. to 100 mg Magnesium)/100 ml Oral Solution (For Veterinary Use Only)	Improves milk production in dairy cattle Increases Lactation period Increase Meat production Prevent Milk Fever in cow Prevents Rickets, Osteomalacia and other diseases related to deficiency of Calcium, Phosphorous, Magnesium, Vitamin D_3 and Vitamin B_{12} Improves physiological functions of the animal Reduce problems due to Calcium deficiency at Last Trimester in pregnancy.	**Contraindication:** Contraindicated to animal hypersensitive to any ingredients of the product. **Side effects:** No side effects are observed at a recommended dose.	New	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
03	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	a) Zinc 0.60gm/100ml Oral Solution (Vet) Zinc Sulphate Monohydrate BP 1.647gm eq. to Zinc 0.60gm/100ml (For Veterinary Use Only)	Strong bone & rapid growth increase the production of eggs & fertility, for the supportive treatment of diarrhea & to increase the body's defense mechanism.	**Contraindications:** Should not be taken at the same time as the antibiotic (tetracycline) because it interferes with the absorption & effectiveness of this medication. **Side Effects:** There is no side effect at the recommended dosage**.**	10mg/5ml	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		b) Oxytetracycline 1000mg Bolus Tablet (Vet) Oxytetracycline Hydrochloride BP 1079.28mg eq. to Oxytetracycline 1000mg (For Veterinary Use Only)	Cattle, Bultalo, Sheep and Goat: Anthrax, haemorrhagic septicaemia, black quarter, rinderpest, brucellosis, pyebnephritis, calf scour, infectious enteritis, malignant edema, dysentery, pneumonia, navel ill, liver infection, abscess, mastitis, pyometra, metritis, peritonitis, kiptospirosis, infectious plauropneumonia, calf diphtheria, castration, paratyphoid, foot-rot, salmonellosis, actinomycosis, anaplasmosis and secondary infections in FMD. Dog, Cat: Pneumonia, pleurisy, bronchitis, infectious enteritis and secondary infections in distemper.	**Contraindications:** Oxytetracycline is contraindicated in animals hypersensitive to active ingredients. **Side Effects:** General toxicity is low although collapse has been reported with tetracycline in weak and debilitated animals.	500mg Bolus	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	Jl‡ai bvg I †RvbvwiK bvg	wb‡`kbv	Contra-indication & Side-effect	Status (New Molecule/ Existing)	‡UKwbK¨vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Incepta Pharmaceuticals Ltd (Dhamrai Unit).	c) Triclabendazole 1800mg + Levamisole 1200mg Bolus Tablet (Vet) Triclabendazole INN 1800 mg + Levamisole HCl BP 1414.39mg eq. to Levamisole 1200 mg (For Veterinary Use Only)	Combination of Triclabendazole & Levamisole bolus is a broad spectrum anthelmintic used against helminths in cattle, buffalo, sheep, goat etc. The drug is used for the treatment of acute, sub acute and chronic fascioliasis due to early immature, immature and adult stages of Fasciola hepatica & Fasciola gigantica. It is also used against major parasites of ruminant such as Haemonchus and Ostertagia of the abomasum; Cooperia, Trichostrongylus and Bunostomum of the small intestine; Oesophagustomum, Trichuris of the large intestine & Dictyocaulus spp. of the lungs. It is also successful in treating eye worms (Thelazia) of cattle.	**Contraindications:** Combination of Triclabendazole & Levamisole bolus is contraindicated in animals hypersensitive to active ingredients. **Side Effects:** Combination of Triclabendazole & Levamisole bolus is well tolerated by the animals. At the recommended doses, side effect is relatively nil.	Triclabendazole 900mg+ Levamisole 600mg Bolus Tablet	Abyôv`b Kiv †h‡Z cv‡i	Abyôv`b Kiv nj
		d) Colistin Sulphate 100,000,000 IU + Gentamicin Sulphate 6000mg/100gm Sachet Powder (Vet) Colistin Sulfate BP 5.2630mg eq. to 100,000,000 IU + Gentamicin Sulfate BP 6000mg/100g (For Veterinary Use Only)	• Intestinal disease caused by Gram-Negative bacillus • Colibacillosis disease such as parahepatitis, airsacculitis, pericarditis, peritonitis & salpingitis etc. • Bacteroidal diarrhea caused by colibacillosis, salmonella, typhia, paratyphoid, pasteurella multocida and so on. • Swine's pleurisy, piglet's yellow, white diarrhea. • Early chick mortality due to E.coli, salmonella spp. And Pseudomonas spp. • C.R.D. (Chronic Respiratory Disease) • Paratyphoid infections • Infectious Coryza • Reduction and elimination of microorganisms like Mycoplasma and salmonella from hatching eggs.	**Contraindications:** It is contraindicated to patients with renal dysfunction and known hypersensitivity to any component of the formulation. **Side Effects:** • Nephrotoxicity • Neurotoxicity • Bronchospasm etc.	New	Abyôv`b Kiv †h‡Z cv‡i	Abyôv`b Kiv nj

2.4 Proposed Product for Import (Human):

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †Rvbv‡iK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-Kvgv‡Ui 63 Zg mfvi wm×vš	mfvi wm×vš
01	**Manufacturer:** Novartis Pharma AG, Switzerland. (Novartis Bangladesh Ltd)	a) Cosentyx 150mg/1ml Solution for Injection in Pre-filled Syringe Secukinumab INN 150mg/1ml **Antipsoriasis**	Secukinumab is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.	**Contraindication:** • Severe hypersensitivity reactions to the active substance or any of the excipients. • Clinically important, active infection (e.g. active tuberculosis) **Side effects:** Common side effects are Upper respiratory tract infections, diarrhoea, Rhinorrhea, oral herpes, Urticaria	EMA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		b) Cosentyx 150mg/1ml Solution for Injection in Pre-filled Pen (auto injector) Secukinumab INN 150mg/1ml **Antipsoriasis**	Secukinumab is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy.	**Contraindication:** • Severe hypersensitivity reactions to the active substance or any of the excipients. • Clinically important, active infection (e.g. active tuberculosis) **Side effects:** Common side effects are Upper respiratory tract infections, diarrhoea, Rhinorrhea, oral herpes, Urticaria	EMA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
02	**Manufacturer:** Novartis Farma S.p.A., Italy. (Novartis Bangladesh Ltd)	a) Sintrom 4 mg tablet Acenocoumarol BP4 mg **Anticoagulant**	Treatment and prevention of thromboembolic diseases.	**Contraindication:** • Known hypersensitivity to Acenocoumarol and related coumarin derivatives or to any of the excipients. • Pregnancy • Patients unable to cooperate (e.g. unsupervised senile patients, alcoholics and patients with psychiatric disorders). • Sintrom is also indicated in conditions where the risk of haemorrhage exceeds the possible clinical benefit, e.g. hemorrhagic diathesis, shortly before or after surgery on the central nervous system or eyes or traumatizing surgery involving extensive exposure of tissues, peptic ulcers or haemorrhage in the gastrointestinal tract, urogenital tract or respiratory system, cerebrovascular haemorrhage, pericarditis, pericardial effusion and infective endocarditis, severe hypertension, severe hepatic or renal impairment, increased fibrinlytic activity following operations on the lung, prostate, uterus etc. **Side effects:** Haemorrhage, Vascular disorders, Gastrointestinal disorders.	Italy & Swiss	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RMbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KvgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
03	**Alkermes Gainesville LLC, USA** (Novartis Bangladesh Ltd)	a) Ritalin LA 10 mg Modified-Release Capsule Methylphenidate Hydrochloride USP10 mg **CNS Stimulant**	Ritalin LA is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).	**Contraindication:** **Agitation:** Ritalin LA (Methylphenidate HCL) extended release capsules is contraindicated in marked anxiety, tension and agitation since the drug may aggravate these symptoms. **Hypersensitivity to Methylphenidate:** Ritalin LA is contraindicated in patients known to be hypersensitive to Methylphenidate or other components of the product. **Glaucoma:** Ritalin LA is contraindicated in patients with Glaucoma. **Tics:** Ritalin LA is contraindicated in patients with motor tics or with a family history or diagnosis of Tourette's syndrome. **Monoamine Oxidase Inhibitors:** Ritalin LA is contraindicated during treatment monoamine oxidase inhibitors and also within a minimum of 14 days following discontinuation of treatment with a monoamine oxidase inhibitor. **Side effects:** Insomnia, anxiety, Nasopharyngitis, decreased appetite, Nervousness, restlessness, sleep disorder, agitation, dyskinesia, tremor, headache, drowsiness, dizziness, tachycardia, palpitation, arrhythmias, changes in blood pressure and heart rate, cough, nausea, dry mouth, rash, pruritus, urticaria, fever, scalp hair loss, hyperhidrosis, feeling jittery, arthralgia & weight decreased.	USA	Abyôgv`b Kiv †h‡Z cv‡i|	Abyôgv`b Kiv nj|
		b) Ritalin LA 20 mg Modified-Release Capsule Methylphenidate Hydrochloride USP 20 mg **CNS Stimulant**	Ritalin LA is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).	-do-	USA	Abyôgv`b Kiv †h‡Z cv‡i|	Abyôgv`b Kiv nj|

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RMbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KvgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
04	**Manufacturer:** Glaxo Operation UK Limited United Kingdom **MAH:** Glaxo Group Limited, United Kingdom **(GlaxoSmithKline Bangladesh Limited)**	a) Anoro Ellipta 62.5mcg/25 mcg Inhalation Powder, Pre-dispensed Umeclidinium bromide INN 74.2mcg eq. to 62.5mcg of Umeclidinium + Vilanterol trifenatate micronized INN 40mcg is eq. to 25 mcg of Vilanterol **Anticholinergic + β2 adrenergic agonist**	It is indicated for the long-term, once-daily, maintenance treatment of air flow obstruction in patients with chronic obstructive pulmonary disease (COPD). **Important limitations:** Not indicated for the relief of acute bronchospasm or for the treatment of asthma.	**Contraindication:** Severe hypersensitivity to milk proteins or any ingredients. **Side effect:** Most common adverse reactions (incidence ≥1% and more common than placebo) include pharyngitis, sinusitis, lower respiratory tract infection, constipation, and diarrhea, pain in extremity, muscle spasms, neck pain, and chest pain.	EMA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		b) Relvar Ellipta 100mcg/25 mcg Inhalation powder, Pre-dispensed Fluticasone Furoate micronized INN 100 mcg + Vilanterol Trifenatate micronized INN 40 mcg equivalent to 25 mcg Vilanterol **Corticosteroid + β2 adrenergic agonist**	**Asthma:** Indicated for the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate: • patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta2-agonists **COPD:** Indicated for the symtomatic treatment of adults with COPD with a FEV_1< 70% predicate normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy.	**Contraindication:** Hypersensitivity to the active substances or to any of the excipients. **Side effect:** Pneumonia, Upper respiratory tract, infection, Bronchitis , Influenza, Candidiasis of mouth and throat, Headache, Abdominal pain, Arthralgia, Back pain, Fractures, Pyrexia, Nasopharyngitis, Oropharyngeal pain, Sinusitis, Pharyngitis, Rhinitis, Cough, Dysphonia	EMA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RMbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Manufacturer: Glaxo Operation UK Limited United Kingdom **MAH:** Glaxo Group Limited, United Kingdom **(GlaxoSmithKline Bangladesh Limited)**	c) Relvar Ellipta 200mcg/25 mcg, Inhalation Powder, Pre-dispensed Fluticasone Furoate micronized INN 200 mcg+ Vilanterol Trifenatate micronized INN 40 mcg eq. 25mcg Vilanterol **Corticosteroid + β2 adrenergic agonist**	**Asthma:** Indicated for the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta2-agonist and inhaled corticosteroid) is appropriate: • patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta2-agonists **COPD:** Indicated for the symtomatic treatment of adults with COPD with a FEV_1< 70% predicate normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy.	**Contraindication:** Hypersensitivity to the active substances or to any of the excipients. **Side effect:** Pneumonia, Upper respiratory tract, infection, Bronchitis , Influenza, Candidiasis of mouth and throat, Headache, Abdominal pain, Arthralgia, Back pain, Fractures, Pyrexia, Nasopharyngitis, Oropharyngeal pain, Sinusitis, Pharyngitis, Rhinitis, Cough, Dysphonia	EMA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj
		d) Incruse Ellipta 62.5mcg Inhalation Powder, Pre-dispensed Umeclidinium Bromide micronized INN 74.2 mcg eq. to 62.5 mcg Umeclidinium **Anticholinergic**	It is an anticholinergic indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD).	**Contraindication:** Severe hypersensitivity to milk proteins and hypersensitivity to any ingredient. **Side effect:** Most common adverse reactions (incidence ≥2% and more common than placebo) include nasopharyngitis, upper respiratory tract infection, cough and arthralgia.	EMA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RMbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
05	**Manufacturer:** Glaxo Operation UK Limited United Kingdom **MAH:** ViiV Healthcare UK Limited, United Kingdom **(GlaxoSmithKline Bangladesh Limited)**	a) Tivicay 50 mg Film Coated Tablet Dolutegravir Sodium INN 52.6mg equivalent to 50mg Dolutegravir **Antiviral**	It is indicated in combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV) infection in combination with other antiretroviral agents in adults and children over 12 years of age.	**Contraindication:** Contraindicated in patients with known hypersensitivity to dolutegravir or to any of the excipients. Co-administration with dofetilide or pilsicainide. **Side effect:** **Allergic reactions:** skin rash,a high temperature (fever), lack of energy (fatigue), swelling, sometimes of the face or mouth (angioedema), causing difficulty in breathing muscle or joint aches. **Very common side effects:** Headache, diarrhea, feeling sick (nausea). Common side effects: Rash, itching (pruritus), being sick (vomiting), stomach pain (abdominal pain) stomach (abdominal) discomfort, Insomnia, dizziness, abnormal dreams, lack of energy (fatigue), wind (flatulence), increase in the level of liver enzymes, enzymes produced in the muscles (creatine phosphokin	EMA	Abyôv`b Kiv †h‡Z cv‡i		Abyôv`b Kiv nj	
06	**Manufacturer:** GlaxoSmithKline Manufacture S.p.A Italy **MAH:** Glaxo Group Ltd, United Kingdom **(GlaxoSmithKline Bangladesh)**	a) Benlysta 120 mg powder for concentrate for solution for infusion Belimumab INN 120mg /Vial **Immunosuppressant**	It is indicated as add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g positive anti-dsDNA and low complement) despite standard therapy	**Contraindication:** Hypersensitivity to the active substances or to any of the excipients. **Side effect:** Bacterial Infections, e.g. bronchitis, cystitis, Gastroenteritis viral, pharyngitis, nasopharyngitis, Leucopenia, Hypersensitivity reactions, Anaphylactic reaction, angioedema, Delayed-type, non-acute hypersensitivity reactions, Depression, insomnia, Migraine, Diarrhoea, nausea, Urticaria, rash, Pain in extremity, Infusion-related reactions, pyrexia.	EMA	Abyôv`b Kiv †h‡Z cv‡i		Abyôv`b Kiv nj	
		b) Benlysta 400 mg powder for concentrate for solution for infusion Belimumab INN 400 mg / Vial **Immunosuppressant**	Indicated as add-on therapy in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g positive anti-dsDNA and low complement) despite standard therapy	**Contraindication:** Hypersensitivity to the active substances or to any of the excipients. **Side effect:** Bacterial Infections, e.g. bronchitis, cystitis, Gastroenteritis viral, pharyngitis, nasopharyngitis, Leucopenia, Hypersensitivity reactions, Anaphylactic reaction, angioedema, Delayed-type, non-acute hypersensitivity reactions, Depression, insomnia, Migraine, Diarrhoea, nausea, Urticaria, rash, Pain in extremity, Infusion-related reactions, pyrexia.	EMA	Abyôv`b Kiv †h‡Z cv‡i		Abyôv`b Kiv nj	

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RIbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
07	Jenssen Cilag, SpA, Vai C Janssen 04010,Borgo San Michele Italy. (Janata Traders)	a) Edurant Film Coated Tablet Rilpivirine Hydrochloride (BP/USP) 27.5mg eq. to 25mg Rilpivirine **Antiviral**	Edulant (Rilpivirine hydrochloride) in combination with other anti retroviral medicinal product is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in anti retroviral treatment –native adult patient with a viral load <100000 HIV-1 RNA Copies/ml. As with other antiretroviral medicinal product, genotype resistant testing should guide the use of Edurant.	**Contraindication:** Hypersensitivity to the active substance or any of the excipients. Edurant should not be co-administrated with the following medicinal product, as significant decrease in rilpivirine plasma concentration may occur, which may result in loss of therapeutic effect of Edurant-the anticonvulsants carbamazipine, oxcarbamazipine, phenobarbital, phenyoin; the antimycobacterials rifapmicin, rifapentine; Proton Pump Inhibitors such as omeprazole, esmoprazole, lansoprazole, pantoprazole. Rebeprazole; the systemic glucocorticoid dexamethasone, except as a single dose treatment; St john's wort. **Side effects:** Appetite depression, insomnia headache, dizziness, Nausea, vomiting, abnormal discomfort, skin rush etc. Decrease white blood cell count. Decrease haemoglobin, decreas platelet count is common, increase total chlesterol.increase LDL cholesterol is very common. Decrease appetite, somnolence, fatigue, increase transminases	Italy	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj	
08	Organon (Ireland) Ltd.Drynam Road Sword Company Dublin, Ireland (Janata Traders)	a) Zoely Flim Coated Tablet Nomegestrol Acetate BP/EP 2.5mg + Estradiol Hemihydrate BP/USP/EP 1.5mg **Contraceptive**	Oral Contraception	**Contraindication:** Combined hormonal Contraceptives (cocs) Should not be used in presence of any of the conditions listed below.No epidemiological data are available with 17β – oestradiol containing COCs, but the contraindications for ethinyloestradiol containing COCs are also considered application to the use of zoely.should any of the conditions appear for the first time during the use of zoely the product should be stopped immediately. Presence of history of venous Thrombosis (deep venous thrombosis, pulmonary embolism), Presence or history of arterial thrombosis (myocardial infarction, cerebrovascular accident)or prodarmal condition (e.g. transient ischemic attack, angina pectoris), History of migraine with focal Neurological symptoms; the presence of severe or Multiple risk factor(s) for venous or or arterial thrombosis such as Diabetes mellitus with vascular symptoms, Severe hypertension, Severe dyslipoproteinemia. Hereditary or acquired predisposition for venous or arterial thrombosis, such as APC resistance, antithrombin-iii-deficiency, protein C deficiency,protein S deficiency, hyperhomocysteinaemia and antiphospholipid, antibodies. (Anticardiolipin antibodies, lupus anticoagulent). **Side effects:** Decreased libido, depression, headache, migrane, nausea, acne, abnormal withdrawal bleeding, metrorrhagia, menorrhagia, brest pain, pelvic pain, weight increased	Ireland	Family Planning Department-Gi gZvgZi wfwË‡Z Abyjgv`b Kiv †h‡Z cv‡i	Family Planning Department-Gi gZvgZi wfwË‡Z Abyjgv`b Abyjgv`b Kiv nj	

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RIbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KvgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
09	Laboratoires Merck Sharp & Dohme, France (Janata Traders)	a) Cancidas 50mg/Vial Powder for concentrate for solution for Infusion Caspofungin Acetate EP/USP 55.50mg eq. to 50mg/Vial **Antifungal**	Cancidas is indicated in adult and pediatric patients (3 month and older) for: Treatment of invasive candidiasis in adult and pediatric patients. Treatment of invasive aspergillosis in adult pediatric patient who are refractory to or intolerant of amphotericin B and /or itraconazole. Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior doses of effective antifungal therapy. Empirical therapy for presumed fungal infection (such as candida or Aspergillus) in febrile, neutropaenic adult or pediatric patient.	**Contraindication:** Contraindicated in patient Hypersensitivity ton any component of this product. Sucrose, Mannitol, Glacial acid, Sodium hydroxide (to adjust the pH). **Side effect:** Rash, itching, felling warm, swelling of face, lipsa or throats or difficulty berating. Difficult breathing with wheezing or a rush that have gets worse – patient may be having an allergic reaction to the medicine. Cough ,serious breathing difficulties – if you are in adult and have Invasive aspergillosis you may be experiencing a serious respiratory Problem that could result in respiratory failure. Common side effect is: May affect up to 1 in 10 people; Decreased hemoglobin (decreased oxygen carrying substance in blood) decreased white blood cell. Decreased blood albumin (a type of protein) in blood, decreased potassium or low potassium level in the blood. Headache, Inflammation of the vein, Shortness of breath. Diarrhea, nausea or vomiting. Changes in some laboratory blood tests (including increased values of some liver tests). Itching, rash, skin redness or sweating more than usual, Joint pain chills, fever, Itching at the injection sites.	France	Abyôgv`b Kiv †h‡Z cv‡i|	Abyôgv`b Kiv nj|

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RMbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Laboratoires Merck Sharp & Dohme, France (Janata Traders)	b) Cancidas 70mg/Vial Powder for concentrate for solution for Infusion Caspofungin Acetate EP/USP 77.70mg eq. to 70mg/Vial **Antifungal**	Cancidas is indicated in adult and pediatric patients (3 month and older) for: Treatment of invasive candidiasis in adult and pediatric patients. Treatment of invasive aspergillosis in adult pediatric patient who are refractory to or intolerant of amphotericin B and /or itraconazole. Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior doses of effective antifungal therapy. Empirical therapy for presumed fungal infection (such as candida or Aspergillus) in febrile, neutropaenic adult or pediatric patient.	**Contraindication:** Contraindicated in patient Hypersensitivity ton any component of this product. Sucrose, Mannitol, Glacial acid, Sodium hydroxide (to adjust the pH). **Side effect:** Rash, itching, felling warm, swelling of face, lipsa or throats or difficulty berating. Difficult breathing with wheezing or a rush that have gets worse – patient may be having an allergic reaction to the medicine. Cough ,serious breathing difficulties – if you are in adult and have Invasive aspergillosis you may be experiencing a serious respiratory Problem that could result in respiratory failure. Common side effect is: May affect up to 1 in 10 people; Decreased hemoglobin (decreased oxygen carrying substance in blood) decreased white blood cell. Decreased blood albumin (a type of protein) in blood, decreased potassium or low potassium level in the blood. Headache, Inflammation of the vein, Shortness of breath. Diarrhea, nausea or vomiting. Changes in some laboratory blood tests (including increased values of some liver tests). Itching, rash, skin redness or sweating more than usual, Joint pain chills, fever, Itching at the injection sites.	France	Abyôv`b Kiv †h‡Z cv‡i	Abyôv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RIbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KvgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
10	Janssen Ortho LLC, State road 933 km 0.1 Momey ward garabo,Puerto Rico 00778, USA (Janata Traders)	a) Prezista 400mg Tablet Darunavir Ethanolate BP/EP/USP 433.64mg eq. to 400mg Darunavir **Antiviral**	Prezista (Darunavir) Co-administered with low dose ritonavir is indicated in combination with other antiretroviral medical products for the treatment of patients with human Immunodeficiency Virus (HIV-1) infection. Prezista Co-administrated cobicistat is indicated in combination with other antiretroviral medicinal product for the treatment of Human immunodeficiency virus (HIV-!)infection in adult patient. Prezista 800mg Tablet s may be use to provide suitable dose regimen for the treatment of (HIV-1) infection in adult and pediatric patient patients form the age of 12 years and at least 40kg body weight who are – Antiretroviral therapy (ART)-Naïve ART experienced with no darunavir resistance associated mutations(DRV-RAMs) and who have Plasma HIV-1 RNA is<100,000 copies/ml and CD4+ cell count >_100 cell >_cellx 10 6 /1.In diciding to initiate treatment with prezista In such ART – experience Patients genotypic testing should guide the use of prezista..	**Contraindication:** Hypersensitivity to the active substance or to any of the excipients. Microcrystalline cellulose colloidal anhydrous silica, crospovidine,Megnesium Stearate ,Hypromellose,Macrogol 3350,talc ,Iron Oxide red,titanium dioxide Concomitent treatment with any of the following medicinal products is contraindicated given the expected decrease in plasma concentration of darunavir and cobicistat and potential for loss of therapeutic effect .Applicable to darunavir boosted with either retonavir or cobicistad. Applicable to darunavir boosted with cobicistat.Darunavir ir or boosted with either ritonavir orcobisistat inhabit the elimination of active substance that are highly dependent on CYP3A for clearance which result is increase exposure to the co administrated medicinal product. Therefore concomitant treatment with such medicinal products for which elevated plasma concentration are associated with serious and or life threatening event is contraindicated these active substance is include: Alfuzosin,amiodarone,bipridil ,dronidarone ,quinidine,ranolazine,systemic lidocain, Astemizole, terfenadine, cholchicine when used in patients with renal or hepatic impairment.ergot derivatives,cisapride pimozide, sidenafil, simvastatin and lovastitine. **Side Effects:** Diarrhea, vomiting, nausea, abdominal apin, increased blood amylase, abdominal distension, flatulence, insomnia	EMA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RIbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Janssen Ortho LLC, State road 933 km 0.1 Momey ward garabo,Puerto Rico 00778, USA (Janata Traders)	b) Prezista 600mg Tablet Darunavir Ethanolate BP/EP/USP 650.46mg eq. to 600mg Darunavir **Antiviral**	Prezista (Darunavir) Co-administered with low dose ritonavir is indicated in combination with other antiretroviral medical products for the treatment of patients with human Immunodeficiency Virus (HIV-1) infection. Prezista Co-administrated cobicistat is indicated in combination with other antiretroviral medicinal product for the treatment of Human immunodeficiency virus (HIV-!)i nfection in adult patient. Prezista 800mg Tablet s may be use to provide suitable dose regimen for the treatment of (HIV-1) infection in adult and pediatric patient patients form the age of 12 years and at least 40kg body weight who are – Antiretroviral therapy (ART)- Naïve ART experienced with no darunavir resistance associated mutations(DRV-RAMs) and who have Plasma HIV-1 RNA is<100,000 copies/ml and CD4+ cell count >_100 cell >_cellx 10 6 /1.In diciding to initiate treatment with prezista In such ART – experience Patients genotypic testing should guide the use of prezista..	**Contraindication:** Hypersensitivity to the active substance or to any of the excipients. Microcrystalline cellulose colloidal anhydrous silica, crospovidine,Megnesium Stearate ,Hypromellose,Macrogol 3350,talc ,Iron Oxide red,titanium dioxide Concomitent treatment with any of the following medicinal products is contraindicated given the expected decrease in plasma concentration of darunavir and cobicistat and potential for loss of therapeutic effect .Applicable to darunavir boosted with either retonavir or cobicistad. Applicable to darunavir boosted with cobicistat.Darunavir ir or boosted with either ritonavir orcobisistat inhabit the elimination of active substance that are highly dependent on CYP3A for clearance which result is increase exposure to the co administrated medicinal product. Therefore concomitant treatment with such medicinal products for which elevated plasma concentration are associated with serious and or life threatening event is contraindicated these active substance is include: Alfuzosin,amiodarone,bipridil ,dronidarone ,quinidine,ranolazine,systemic lidocain, Astemizole, terfenadine, cholchicine when used in patients with renal or hepatic impairment.ergot derivatives,cisapride pimozide, sidenafil, simvastatin and lovastitine. **Side Effects:** Diarrhea, vomiting, nausea, abdominal apin, increased blood amylase, abdominal distension, flatulence, insomnia	EMA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RIbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Janssen Ortho LLC, State road 933 km 0.1 Momey ward garabo,Puerto Rico 00778, USA (Janata Traders)	c) Prezista 800mg Tablet Darunavir Ethanolate BP/EP/USP 867.28mg eq. to 800mg Darunavir **Antiviral**	Prezista (Darunavir) Co-administered with low dose ritonavir is indicated in combination with other antiretroviral medical products for the treatment of patients with human Immunodeficiency Virus (HIV-1) infection. Prezista Co-administrated cobicistat is indicated in combination with other antiretroviral medicinal product for the treatment of Human immunodeficiency virus (HIV-!) infection in adult patient. Prezista 800mg Tablet s may be use to provide suitable dose regimen for the treatment of (HIV-1) infection in adult and pediatric patient patients form the age of 12 years and at least 40kg body weight who are – Antiretroviral therapy (ART)- Naïve ART experienced with no darunavir resistance associated mutations (DRV-RAMs) and who have Plasma HIV-1 RNA is<100,000 copies/ml and CD4+ cell count >_100 cell >_cellx 10 6 /1.In diciding to initiate treatment with prezista In such ART – experience Patients genotypic testing should guide the use of prezista..	**Contraindication:** Hypersensitivity to the active substance or to any of the excipients. Microcrystalline cellulose colloidal anhydrous silica, crospovidine,Megnesium Stearate ,Hypromellose,Macrogol 3350,talc ,Iron Oxide red,titanium dioxide Concomitent treatment with any of the following medicinal products is contraindicated given the expected decrease in plasma concentration of darunavir and cobicistat and potential for loss of therapeutic effect .Applicable to darunavir boosted with either retonavir or cobicistad. Applicable to darunavir boosted with cobicistat.Darunavir ir or boosted with either ritonavir orcobisistat inhabit the elimination of active substance that are highly dependent on CYP3A for clearance which result is increase exposure to the co administrated medicinal product. Therefore concomitant treatment with such medicinal products for which elevated plasma concentration are associated with serious and or life threatening event is contraindicated these active substance is include: Alfuzosin,amiodarone,bipridil ,dronidarone ,quinidine,ranolazine,systemic lidocain, Astemizole, terfenadine, cholchicine when used in patients with renal or hepatic impairment.ergot derivatives,cisapride pimozide, sidenafil, simvastatin and lovastitine. **Side Effects:** Diarrhea, vomiting, nausea, abdominal apin, increased blood amylase, abdominal distension, flatulence, insomnia	EMA	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
12	Janssen-Cilag S.p.A Vai C.Janssen,Borgo San Michele, 04100 Latina,Italy (Janata Traders)	a) Olysio Capsule, Hard Simeprevir Sodium alt-spray dried powder BP/EP/USP 154.40mg eq. to 150mg Simeprevir **Antiviral**	Olysio (Simeprevir) is indicated in combination with other medicinal product s for the treatment of chronic hepatitis C (CHC) in adult patient.	**Contraindication:** Hypersensitivity to the active substance or to any of the excipient listed below: capsule content sodium lauryl sulfate, Megnesium srearate ,colloidal anhydrous sillica ,Croscarmellose sodium,Lactose mono hydrate, Capsule shell: Gelatin Titanium dioxaide, Black printing ink **Side effect:** During the first 12 weeks of treatment, the most frequent reported adverse reaction (incidence > 5%) were nausea, rash, pruritus, Dyspnoea, blood bilirubin increase and photosensitivity reaction, Hepatic impairment.	Italy	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RMbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
13	Octa pharma SAS, France (Discount Pharma. 30, Bir Uttam K.M. Shafiullah Road. Dhaka.)	a) Albunorm 5% (250ml /12.5gm) Human Albumin Solution 250ml /12.5gm	Restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate. Albunorm 5% is indicated for Burn, Liver failure, Liver cirrhosis, Nephritis, Nephrotic syndrome, Gastritic and intestinal disorders, Lyell's syndrome, Ascites, Adult respiratory distress syndrome, Cerebral edema, Toxemia of pregnancy.	**Contraindications:** Hypersensitivity to albumin preparations or to any of the excipients. **Side Effects:** Mild reactions such as flush, urticaria, fever and nausea occur rarely. These reactions normally disappear rapidly when the infusion rate is slowed down or the infusion is stopped. Very rarely, severe reactions such as shock may occur. In case of severe reactions, the infusion should be stopped and an appropriate treatment should be initiated.	France	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
		b) Albunorm 20% (50ml/ 10 gm) Human Albumin Solution (50ml/ 10 gm)	Restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate. Albunorm 5% is indicated for Burn, Liver failure ,Liver cirrhosis, Nephritis, Nephrotic syndrome, Gastritic and intestinal disorders, Lyell's syndrome, Ascites, Adult respiratory distress syndrome, Cerebral edema, Toxemia of pregnancy.	**Contraindications:** Hypersensitivity to albumin preparations or to any of the excipients. **Side Effects:** Mild reactions such as flush, urticaria, fever and nausea occur rarely. These reactions normally disappear rapidly when the infusion rate is slowed down or the infusion is stopped. Very rarely, severe reactions such as shock may occur. In case of severe reactions, the infusion should be stopped and an appropriate treatment should be initiated.	France	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
		c) Albunorm 20% (100m/ 20gm) Human Albumin Solution 100m/ 20gm	Restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate. Albunorm 20% is indicated for Burn, Liver failure, Liver cirrhosis, Nephritis, Nephrotic syndrome, Gastritic and intestinal disorders, Lyell's syndrome, Ascites, Adult respiratory distress syndrome, Cerebral edema, Toxemia of pregnancy.	**Contraindications:** Hypersensitivity to albumin preparations or to any of the excipients. **Side Effects:** Mild reactions such as flush, urticaria, fever and nausea occur rarely. These reactions normally disappear rapidly when the infusion rate is slowed down or the infusion is stopped. Very rarely, severe reactions such as shock may occur. In case of severe reactions, the infusion should be stopped and an appropriate treatment should be initiated.	France	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RIbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KvgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Octa pharma SAS, France (Discount Pharma. 30, Bir Uttam K.M. Shafiullah Road. Dhaka.)	d) Albunorm 25% (50ml/12.5gm) Human Albumin Solution 50ml/12.5gm	Restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate. Albunorm 20% is indicated for Burn, Liver failure ,Liver cirrhosis, Nephritis, Nephrotic syndrome, Gastritic and intestinal disorders, Lyell's syndrome, Ascites, Adult respiratory distress syndrome, Cerebral edema, Toxemia of pregnancy.	**Contraindications:** Hypersensitivity to albumin preparations or to any of the excipients. **Side Effects:** Mild reactions such as flush, urticaria, fever and nausea occur rarely. These reactions normally disappear rapidly when the infusion rate is slowed down or the infusion is stopped. Very rarely, severe reactions such as shock may occur. In case of severe reactions, the infusion should be stopped and an appropriate treatment should be initiated.	France	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
		e) Albunorm 25% (100ml/25gm) Human Albumin Solution 100ml/25gm	Restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate. Albunorm 25% is indicated for Burn, Liver failure ,Liver cirrhosis, Nephritis, Nephrotic syndrome, Gastritic and intestinal disorders, Lyell's syndrome, Ascites, Adult respiratory distress syndrome, Cerebral edema, Toxemia of pregnancy.	**Contraindications:** Hypersensitivity to albumin preparations or to any of the excipients. **Side Effects:** Mild reactions such as flush, urticaria, fever and nausea occur rarely. These reactions normally disappear rapidly when the infusion rate is slowed down or the infusion is stopped. Very rarely, severe reactions such as shock may occur. In case of severe reactions, the infusion should be stopped and an appropriate treatment should be initiated.	France	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
14	Pharmacia and Upjohn Co. USA for Pfizer Inc., USA (Radiant Export Import Enterprise. Uttara, Dhaka.)	a) Eraxis Lyophilized powder for injection Anidulafungin 100mg/vial INN **Antifungal**	Treatment of invasive candidiasis	**Contraindication**: Persons with known hypersensitivity to anidulafungin, any component of ERAXIS, or other echinocandins **Side effects**: Diarrhea, nausea, vomiting, flashing, convulsion, headache, coagulopathy, hypokalaemia, raised serum creatinine, rash, pruritus; less commonly abdominal pain, cholestasis, hypertension, hyperglycemia, urticarial, injection-site pain; also reported, hypotension dyspnea, bronchospasm, hepatitis.	FSC-USFDA	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RIbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KvgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
15	Fresinius Kabi AB, Uppsala, Sweden (Radiant Export Import Enterprise. Uttara, Dhaka.	a) Kabiven Central Emulsion for Infusion, 1026ml (Three chamber inner bag with peeble seals) 1st chamber includes : Glucose 19% to 526ml 2nd Chamber : Amino Acid 300ml 3rd chamber Intralipid 20% to 200ml **Parenteral Nutrition**	Parenteral nutrition for adult patients and children above 2 years of age when oral or enteral nutrition is impossible or insufficient or contraindicated.	**Contraindication:** a) Hypersensitivity to egg, soya or peanut protein or to any of the ingredients. b) Severe hyperlipaemia c) Severe blood coagulation disorders d) Inborn errors of amino acid metabolism e) severe renal insufficiency without access to haemofiltration or dialysis f) Acute shock g) Hyperglycaemia, Which requires more than 6 units insulin/h h) Pathologically elevated serum levels of any of the included electrolytes i) Haemophagocytotic syndrome j) Due to composition, Kabiven is not suitable for use in new brons or infants under 2 years of age. **Side effects:** Fat overload syndrome Intralipid may cause a rise in body temperature (incidence <3%) and, less frequently, shivering, chills and nausea/vomiting (incidence <1%). Transient increases in liver enzymes during intravenous nutrition have also been reported. As with all hypertonic solutions for infusion, thrombophlebitis may occur if peripheral veins are used. Reports of other undesirable effects in conjunction with Intralipid infusions are extremely rare; less than one adverse event per million infusions. Hypersensitivity reactions (anaphylactic reaction, skin rash, urticaria), respiratory symptoms (e.g. tachypnoea) and hyper/hypotension have been described. Haemolysis, reticulocytosis, abdomi nal pain, headache, tiredness and priapism have been reported.	Sweden	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RIbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KvgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Fresinius Kabi AB, Uppsala, Sweden (Radiant Export Import Enterprise. Uttara, Dhaka.	b) Kabiven Perifer, Emulsion for Infusion, 1440ml (Three chamber inner bag with peeble seals) 1st chamber includes : Glucose 11% to 885ml 2nd Chamber : Amino Acid 300ml 3rd chamber Intralipid 20% to 255ml **Parenteral Nutrition**	Parenteral nutrition for adult patients and children above 2 years of age when oral or enteral nutrition is impossible or insufficient or contraindicated.	**Contraindication:** a) Hypersensitivity to egg, soya or peanut protein or to any of the ingredients . b) Severe hyperlipaemia c) Severe blood coagulation disorders d) Inborn errors of amino acid metabolism e) severe renal insufficiency without access to haemofiltration or dialysis f) Acute shock g) Hyperglycaemia, Which requires more than 6 units insulin/h h) Pathologically elevated serum levels of any of the included electrolytes i) Haemophagocytotic syndrome j) Due to composition, Kabiven is not suitable for use in new brons or infants under 2 years of age. **Side effects**. The infusion may cause a rise in body temperature (incidence <3%) and, less frequently, shivering, chills and nausea/vomiting (incidence <1%). Transient increases in liver enzymes during intravenous nutrition have also been reported. Reports of other undesirable effects in conjunction with the included components are Extremely rare. Hypersensitivity reactions (anaphylactic reaction, skin rash, urticaria), respiratory symptoms (e.g. tachypnoea) and hyper/ hypotension have been described. Haemolysis, reticulocytosis, abdominal pain, headache, nausea, vomiting, tiredness and priapism have been reported.	Sweden	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RMbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KvgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
16	CP Pharmaceuticals Limited for Wockhardt UK ltd., (MAH), United Kingdom. (Radiant Export Import Enterprise. Uttara, Dhaka. | a) Sodium Valproate Wockhardt Solution for Injection or Infusion. Sodium Valproate EP 100 mg / ml (400 mg/ 4 ml ampoule) **Antiepileptic**	The treatment of epileptic patients who would normally be maintained on oral sodium valproate, and for whom oral therapy is temporarily not possible.	**Contraindications:** - Active liver disease - Personal or family history of severe hepatic dysfunction, especially drug related - Hypersensitivity to sodium valproate - Porphyria **Side Effects:** -Hepato-biliary disorders: rare cases of liver injury. -Gastrointestinal disorders: (nausea, gastralgia, diarrhoea) frequently occur at the start of treatment, but they usually disappear after a few days without discontinuing treatment. -Nervous system disorders: Sedation has been reported occasionally, usually when in combination with other anticonvulsants -Psychiatric disorder: Confusion has been reported -Metabolic disorders: Cases of isolated and moderate hyperammonaemia without change in liver function tests may occur frequently are usually transient and should not cause treatment discontinuation.	UK FSC-MHRA	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj	
17	DSM Pharmaceuticals INC., USA For Roche Pharma, Switzerland (Roche Bangladesh Limited., Dhaka)	a) Kadcyla 100mg/Vial Powder for the preparation of an infusion solution concentrate Trastuzumab Emtansine INN 106mg eq. to 100mg Trastuzumab **Anticancer**	Kadcyla, as a single agent, is indicated for the treatment of patients with HER2-positive, unresectable locally advanced or metastatic breast cancer who have received prior treatment with trastuzumab and a taxane.	**Contraindications:** This product is contraindicated in patients with a known hypersensitivity to kadcyla or any of its excipients. **Side Effects:** Side effect includes diarrhoea, constipation, abdominal pain, dry mouth, dyspepsia, gingival bleeding, left ventricular dysfunction, hypertension, peripheral oedema, epistaxis, cough, dyspnoea, insomnia, peripheral neuropathy, headache, dizziness, dysgeusia, memory impairment, malaise, pyrexia, chills, urinary tract infection, thrombocytopenia, haemorrhage, hypokalaemia, infusion-related reactions, arthralgia, myalgia, dry eye, conjunctivitis, blurred vision, increased lacrimation, rash, pruritus, nail disorder, urticaria, hand-foot syndrome; less commonly interstitial lung disease including pneumonitis, hepatic toxicity and failure, nodular regenerative hyperplasia, portal hypertension	CPP-Switzerland & USA	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj	

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RIbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KvgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	DSM Pharmaceuticals INC., USA For Roche Pharma, Switzerland (Roche Bangladesh Limited., Dhaka)	b) Kadcyla 160mg/Vial Powder for the preparation of an infusion solution concentrate Trastuzumab Emtansine INN 171mg eq. to 160mg Trastuzumab **Anticancer**	Kadcyla, as a single agent, is indicated for the treatment of patients with HER2-positive, unresectable locally advanced or metastatic breast cancer who have received prior treatment with trastuzumab and a taxane.	**Contraindications:** This product is contraindicated in patients with a known hypersensitivity to kadcyla or any of its excipients. **Side Effects:** Side effect includes diarrhoea, constipation, abdominal pain, dry mouth, dyspepsia, gingival bleeding, left ventricular dysfunction, hypertension, peripheral oedema, epistaxis, cough, dyspnoea, insomnia, peripheral neuropathy, headache, dizziness, dysgeusia, memory impairment, malaise, pyrexia, chills, urinary tract infection, thrombocytopenia, haemorrhage, hypokalaemia, infusion-related reactions, arthralgia, myalgia, dry eye, conjunctivitis, blurred vision, increased lacrimation, rash, pruritus, nail disorder, urticaria, hand-foot syndrome; less commonly interstitial lung disease including pneumonitis, hepatic toxicity and failure, nodular regenerative hyperplasia, portal hypertension	Switzerland, USA	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
18	Patheon INC., Canada For Hoffmann-LA Roche Ltd., Switzerland (Roche Bangladesh Limited., Dhaka)	a) Erivedge 150mg Capsule Vismodegib INN 150mg **Anticancer**	Indicated for the treatment of adult Patients with advanced basal cell carcinoma for whom surgery is inappropriate.	**Contraindications:** This product is contraindicated in nursing mothers during the courses of treatment and for 7 (seven) months after the last dose because of the potential to cause serious development defects in breast fed infants and children. **Side Effects:** nausea, vomiting, diarrhoea, constipation, abdominal pain, decreased appetite, weight loss, dehydration, dyspepsia, taste disturbances, malaise, amenorrhoea, hyponatraemia, arthralgia, musculoskeletal pain, muscle spasms, alopecia, abnormal hair growth, pruritus, rash	Canada	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RIbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KvgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
19	Novo Nordisk A/S Novo Alle, DK 2880 Bagsvaerd, Denmark	a) Vagifem® 10 micrograms, 18/24 vaginal tablets with applicators Estradiol Hemihydrates 10.3mcg eq. to estradiol 0.0100mg **Hormone**	Treatment of vaginal atrophy due to oestrogen deficiency in postmenopausal women.	**Contraindication:** ➢ Known, past or suspected breast cancer ➢ Known, past or suspected oestrogen-dependent malignant tumours (e.g. endometrial cancer) ➢ Undiagnosed genital bleeding ➢ Untreated endometrial hyperplasia ➢ Previous or current venous thromboembolism (deep venous thrombosis, pulmonary embolism) ➢ Known thrombophilia disorders ➢ Active or recent arterial thromboembolic disease (e.g. angina, myocardial infarction) ➢ Acute liver disease, or a history of liver disease as long as liver function tests have failed to return to normal ➢ Known hypersensitivity to the active substances or to any of the excipients ➢ Porphyria. **Undesirable Effects:** Common (≥ 1/100; < 1/10) ➢ Nervous system disorders: headache ➢ Gastrointestinal disorders: abdominal pain ➢ Reproductive system and breast disorders: vaginal haemorrhage, vaginal discharge or vaginal discomfort. Uncommon (≥ 1/1,000; < 1/100) ➢ Infections and infestations: vulvovaginal mycotic infection ➢ Gastrointestinal disorders: nausea ➢ Skin and subcutaneous tissue disorders: rash ➢ Investigations: weight increased ➢ Vascular disorders: hot flush, hypertension.	Denmark, Australia	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RMbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
20	Manufactured by: Janssen Pharmaceutica N.V., Belgium **(UniHealth Ltd.** 34/1 Sonagaon Road, Paribag, Dhaka, Bangladesh)	a) Invega Sustenna 50mg Prolonged Release suspension for injection. Paliperidone palmitate 78mg eqv. to 50mg Paliperidone/0.5ml **Antipsychotic**	INVEGA® SUSTENNA® is an atypical antipsychotic indicated for Treatment of schizophrenia. Treatment of schizoaffective disorder as monotherapy and as an adjunct to mood stabilizers or antidepressants.	**Contra-Indication**: Known hypersensitivity to paliperidone, risperidone, or to any excipients in the formulation (4) **Adverse Reactions:** The most common adverse reactions (incidence ≥ 5% and occurring at least twice as often as placebo) were injection site reactions,	FSC-EMA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj	
		b) Invega Sustenna 75mg Prolonged Release suspension for injection Paliperidone palmitate 117mg eq.to 75mg Paliperidone/0.75ml **Antipsychotic**	Do	Do	FSC-EMA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj	
		c) Invega Sustenna 100mg Prolonged release suspension for injection Paliperidone palmitate 156mg eqv.to 100mg Paliperidone/1ml **Antipsychotic**	Do	Do	FSC-EMA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj	

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RMbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KvgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Manufactured by: Janssen Pharmaceutica N.V., Belgium **(UniHealth Ltd.** 34/1 Sonagaon Road, Paribag, Dhaka, Bangladesh)	d) Invega Sustenna 150mg Prolonged release suspension for injection Paliperidone palmitate 234mg Eqv. to 150mg Paliperidone/1.5ml **Antipsychotic**	Do	Do	FSC-EMA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj	
21	Manufactured by: Baxter Pharmaceutical Solutions LLC, USA Released by: Cilag AG, Switzerland **(UniHealth Ltd.** 34/1 Sonagaon Road, Paribag, Dhaka, Bangladesh)	a) Simponi solution for injection in pre-filled syringe Golimumab 100mg/1ml **Immunosuppresant Agent**	SIMPONI, in combination with methotrexate, is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis and psoriatic arthritis. This is also used for treating Ankylosing Spondylitis and Ulcerative Colitis.	**Contra-indications :** No contraindications have been reported. **Adverse Reactions:** As the clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. The most serious adverse reactions were Serious Infections and Malignancies. Upper respiratory tract infection and nasopharyngitis were the most common adverse reactions reported in the combined Phase 3 RA, PsA and AS trials. The use of TNF-blockers, including SIMPONI, has been associated with the formation of autoantibodies and, rarely, with the development of a lupus-like syndrome.	FSC-Switzerland	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj	
		b) Simponi solution for injection in a pre-filled injector (pen) Golimumab 100mg/1ml **Immunosuppresant Agent**	SIMPONI, in combination with methotrexate, is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis and psoriatic arthritis. This is also used for treating Ankylosing Spondylitis and Ulcerative Colitis.	-do-	FSC-Switzerland	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj	

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RIbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK¨vj mve-Kgv‡Ui 63 Zg mfvi wm×vš	mfvi wm×vš
	Manufactured by: Baxter Pharmaceutical Solutions LLC, USA Released by: Cilag AG, Switzerland **(UniHealth Ltd. 34/1 Sonagaon Road, Paribag, Dhaka, Bangladesh)**	c) Simponi solution for injection in pre-filled syringe Golimumab 50mg/0.5ml **Immunosuppresant Agent**	SIMPONI, in combination with methotrexate, is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis and psoriatic arthritis. This is also used for treating Ankylosing Spondylitis and Ulcerative Colitis.	Do	FSC-Switzerland	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
		d) Simponi solution for injection in a pre-filled injector (pen) Golimumab 50mg/0.5ml)	Do	Do	FSC-Switzerland	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj
24	Manufactured by: BSP Pharmaceuticals S.r.l, Italy Released by: Janssen Pharmaceutica N.V., Turnhoutseweg 30, B-2340, Beerse, Belgium **(UniHealth Ltd. 34/1 Sonagaon Road, Paribag, Dhaka, Bangladesh)**	a) Velcade 1mg Powder for Solution for Injection Bortezomib 1mg/Vial **Anticancer**	Bortezomib in combination with melphalan and prednisone is indicated for the treatment of patients with previously untreated multiple myeloma who are not eligible for high-dose chemotherapy with bone marrow transplant. Bortezomib is indicated as monotherapy for the treatment of progressive multiple myeloma in patients who have received at least 1 prior therapy and who have already undergone or are unsuitable for bone marrow transplantation.	**Contra-indications :** Hypersensitivity to Bortezomib, boron or to any of the excipients. Acute diffuse infiltrative pulmonary and pericardial disease. **Adverse Reactions:** The most commonly reported adverse reactions during treatment with Bortezomib are nausea, diarrhoea, constipation, vomiting, fatigue, pyrexia, thrombocytopenia, anaemia, neutropenia, peripheral neuropathy (including sensory), headache, paraesthesia, decreased appetite, dyspnoea, rash, herpes zoster and myalgia. Serious adverse reactions uncommonly reported during treatment with Bortezomib include cardiac failure, tumour lysis syndrome, pulmonary hypertension, reversible posterior leukoencephalopathy syndrome (RPLS), acute diffuse infiltrative pulmonary disorders and rarely autonomic neuropathy	FSC-EMA	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	Jl‡ai bvg I †RvlbviK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK¨vj me-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
25	Manufactured by: Baxter Oncology GmbH, Germany **Released by: Janssen Pharmaceutica N.V., Belgium** **(UniHealth Ltd. 34/1 Sonagaon Road, Paribag, Dhaka, Bangladesh)**	Yondelis Powder for concentrate for solution for infusion Trabectedin 1mg/Vial **Anticancer**	YONDELIS® is indicated for the treatment of adult patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents. Efficacy data are based mainly on liposarcoma and leiomyosarcoma patients. YONDELIS® in combination with pegylated liposomal doxorubicin (PLD) is indicated for the treatment of patients with relapsed platinum-sensitive ovarian cancer.	**Contra-indications :** Patients who are hypersensitive to YONDELIS® (trabectedin) or to any ingredient in the formulation or component of the container. YONDELIS® should not be administered to nursing mothers **YONDELIS® should not be administered to patients with an active serious or uncontrolled infection** **Adverse Reactions:** Like all medicines, YONDELIS® or its combination with CAELYX® can cause side effects, although not everyone gets them. Side effects caused by YONDELIS® treatment: Very common (may affect more than 1 in 10 people) side effects are that you may: feel tired , feel shortness of breath, bruise more easily , have nose bleeds, have a decrease in white blood cells or platelets which may lead to infection or unexpected bruising or bleeding , have blood infections (neutropenic infection and neutropenic sepsis). experience headache and a loss of strength , lose your appetite, feel sick (nausea) or vomit, and become constipated , have diarrhea, loss of water from the body, inflammation of the mouth (stomatitis), pain in the abdomen, weight loss, digestive discomfort and a change in your sense of taste.	FSC-EMA	Abyjgv`b Kiv †h‡Z cv‡i|	Abyjgv`b Kiv nj|

2.5 Proposed Product for Import (Human Vaccine):

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	we‡klÁ KvgwUi gZvgZ	‡UKwbK¨vj mve-KvgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
01	Government Pharmaceutical Organization - Merieux Biological Product Company Limited Thailand. (Sanofi Bangladesh Limited)	a) IMOJEV® Japanese encephalitis virus (live, attenuated, recombinant) 4.0-5.8 log PFU/dose	**Indication-** IMOJEV® is indicated for prophylaxis of Japanese encephalitis caused by the Japanese encephalitis virus, in subjects from 12 months of age and over.	**Contraindication-** IMOJEV® should not be administered to anyone with a history of severe allergic reaction to any component of the vaccine or after previous administration of the vaccine or a vaccine containing the same components or constituents. Vaccination must be postponed in case of febrile or acute disease. Congenital or acquired immune deficiency impairing cellular immunity, including immunosuppressive therapies such as chemotherapy, high doses of systemic corticosteroids given generally for 14 days or more.IMOJEV® must not be administrated to persons with symptomatic HIV infection or with asymptomatic HIV infection when accompanied by evidence of impaired immune function. **Side effects- General disorders and administration site conditions:** Influenza like illness, injection site rash, chest discomfort, injection site reaction, injection site induration, oedema peripheral, irritability, injection site haemorrhage, injection site warmth, injection site paraesthesia, asthenia, injection site joint pain, injection site discomfort, tenderness. **Nervous system disorders:** Sinus headache, lethargy, paraesthesia, migraine, somnolence, syncope vasovagal, dizziness postural **Musculoskeletal and connective tissue disorders:** Back pain, neck pain, pain in extremity, musculoskeletal pain, pain in jaw, musculoskeletal stiffness, muscle spasms, muscle tightness, intervertebral disc compression. **Gastrointestinal disorders:** Abdominal pain upper, dry mouth, lip	**TGA** (Australia)	**WHO wc‡KvqwjdvBW Gi c‡i Abyjgv`‡bi mgwik Kiv nj|**	Abyjgv`b Kiv †h‡Z cv‡i|	Abyjgv`b Kiv nj|

				swelling, dyspepsia, palatal oedema, tongue oedema. **Infections and infestations:** Viral infection, urinary tract infection, gastroenteritis, subcutaneous abscess. **Respiratory, thoracic and mediastinal disorders:** Sneezing, asthma, pharyngeal erythema, throat irritation. **Skin and subcutaneous tissue disorders:** Pruritus, pruritus generalized, rash maculo-papular, rash generalised, swelling face, eczema, urticaria, rash popular, rash macular, rash erythematous. **Investigations:** Alanine aminotransferase increased lymph node palpable. **Injury, poisoning and procedural complications:** Sunburn. **Blood and lymphatic system disorders:** Lymphadenopathy, leukopenia, lymph node pain, lymphopenia. **Psychiatric disorders:** Insomnia. **Ear and labyrinth disorders**: Ear pain, tinnitus, vertigo. **Eye disorders:** Eye pain, vision blurred, eye pruritus, eye swelling. **Vascular disorders:** Flushing, hot flush, hypertension **Cardiac disorders:** Sinus tachycardia. **Immune system disorders:** Hypersensitivity. **Metabolism and nutrition disorders:** Decreased appetite, increased appetite.				

bs	c¯ZKvi‡Ki bvg	Jl‡ai bvg I †RvlbwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	we‡klÁ KvgwUi gZvgZ	‡UKwbK¨vj mve-KvgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
2.	Crucell Sweden AB (Healthcare Pharmaceuticals Ltd., Bangladesh)	a) **Dukoral Vaccine** Oral suspension (vaccine) and effervescent granules (buffer) *Vibrio cholerae* O1 Inaba classic strain, heat inactivated : 31.25 x 10^9 bacteria* *Vibrio cholerae* O1 Inaba El Tor strain, formalin inactivated: 31.25 x 10^9 bacteria* *Vibrio cholerae* O1 Ogawa classic strain, heat inactivated: 31.25 x 10^9 bacteria* *Vibrio cholerae* O1 Ogawa classic strain, formalin inactivated: 31.25 x 10^9 bacteria* **Total: 1.25 x 10^{11} bacteria*** Recombinant cholera toxin B subunit (rCTB): 1 mg *bacterial count before inactivation	**Indicated for active immunization against –** **Cholera:** Active immunisation of adults and children from 2 years of age against cholera infection risk. **ETEC Diarrhea:** Active immunisation of adults and children from 2 years of age against diarrhoeal illness caused by enterotoxigenic Escherichia coli (ETEC).	**Contraindication:** Hypersensitivity to the active substances, to any of the excipients or to formaldehyde. **Side-effect:** The side effects are usually mild. The most common side effects are abdominal pain, diarrhea, nausea and vomiting.			Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj|

2.6 Proposed Product for Import (Veterinary):

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †Rvbv‡iK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	‡UKwbK¨vj mve-Kvgvwi 63 Zg mfvi wm×vš	mfvi wm×vš
01	WooGene B&G Co., Ltd. Korea (ACI Ltd.)	a) Superamino Injectable solution 250ml, 500ml, 1000ml, 5L & 10L L-Valine 8mg+L-Leucine 11mg+L-Isoleucin 5mg+ Arginine HCl 5mg+Histidine HCl 3.5mg+L-Methionine 3mg+L-Phenylalanine 7mg+ L-Threonine 4.6mg+L-Trypophan 2mg+Lysine HCl 10mg+Cysteine HCl 5mg+ Vitamin B1 10mg+ Riboflavine-5-Phosphate sodium 4mg+Calcium Pantothenate 5mg+ Niacinamide 150mg+ Vitamin B6 10mg+Vitamin B12 5µg+Sodium acetate 250mg+Calcium Chloride 2H2O 150mg+Potassium Chloride 200mg+ Magnesium Sulfate 7H2O 200mg + Dextrose H2O 5g +Methyl Paraben 180mg +Propyl Paraben 20mg + Distilled water q.s./100ml	For the supply of high concentration of glucose, vitamin B complexes, amino acids and electrolytes for metabolizing in weakened animals	**Contraindication**: No contraindications are known. **Side Effect**: Reddish color and little pain may occur at the injected site.	KOREA		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		b) Superamino-C Injectable solution 20ml, 50ml, 100ml, 250ml & 500ml L-Valine 136mg+L-Leucine 187mg+L-Isoleucin 85mg+ Arginine HCl 85mg+ Histidine HCl 59.5mg+L-Methionine 51mg+L-Phenylalanine 119mg+L-Threonine 78.2mg+L-Trypophan 34mg+Lysine HCl 170mg+Cysteine HCl 85mg+Vitamin B1 10mg+ Riboflavine-5-Phosphate sodium 4mg+Calcium Pantothenate 5mg+ Niacinamide 150mg+ Vitamin B6 10mg+Vitamin B12 5µg+Sodium acetate 250mg+Calcium Chloride 2H2O 150mg+Potassium Chloride 200mg+ Magnesium Sulfate 7H2O 200mg+Dextrose H2O 5g+Methyl Paraben 180mg+ Propyl Paraben 20mg +Distilled water q.s./100ml	For the supply of high concentration of glucose, vitamin B complexes, amino acids and electrolytes for metabolizing in weakened animals	**Contraindication**: No contraindications are known. **Side Effect**: Reddish color and little pain may occur at the injected site.	KOREA		c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbviK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	WooGene B&G Co., Ltd. Korea (ACI Ltd.)	c) Calci-Max Injectable solution 100ml, 250ml & 500ml Calcium Gluconate monohydrate 450mg+ Calcium Glubionate 20mg+Calcium Acetate monohydrate 37mg+ Magnesium Hypophosphite-6-hydrate 30mg/1ml	For pre & post-parturitional hypocalcemia, milk fever, tetany of pregnancy and lactating, shipping fever, grass tetany of cow (magnesium deficiency), paresis, calcium deficiency syndrome in early pregnancy of cow, sheep goat, Osteomalasia in cow, sheep and goat, disease and weakness of new born animal.	**Contraindication**: No contraindications are known. **Side Effect**: Reddish color and little pain may occur at the injected site.	KOREA		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
02	Ceva Phylaxia Veterinary Biologicals co. Ltd. (ACI Ltd.)	a) Cevac Flu H9 K Vaccine 500ml (1000/2500 doses) Avian Influenza virus (strain H9N2)..inducing min. 5.0 log2 HI+Mineral oil (paraffinum perliquidum)…0.332ml+Sorbitanmonooleat 17.5mg+polysorbat 80..0.067ml+water for injection…ad 0.5ml/dose	Inactivated oil emulsion vaccine stimulates active immunity against Avian Influenza in Chickens.	**Contraindication**: No contraindications are known. **Side Effect:** No palpable reactions were observed following the injection of one dose of vaccine.	HUNGARY		c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj
		b) Cevac New Flu H9 K Vaccine 500ml (1000/2500 doses) Inactivated Newcastle disease virus (strain LaSota)…inducing min 5.0 log2 HI+Avian Influenza virus (strain H9N2)..inducing min. 5.0 log2 HI+ Mineral oil (paraffinum perliquidum)…0.332ml+ Sorbitanmonooleat 17.5mg+polysorbat 80..0.067ml+water for injection…ad 0.5ml/dose	Inactivated oil emulsion vaccine stimulates active immunity against Newcastle disease and Avian Influenza in Chickens.	**Contraindication**: No contraindications are known. **Side Effect**: No palpable reactions were observed following the injection of one dose of vaccine.	HUNGARY		c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbviK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Ceva Phylaxia Veterinary Biologicals co. Ltd. (ACI Ltd.)	c) Cevac Coryza 3 Gel Vaccine 250ml, 500ml & 1500ml (1000doses/500ml) Avibacterium paragallina -rum serotype A…min 7log10 CFU before inactivation+Avibacterium paragallinarum serotype B….min 7log10 CFU before inactivation+Avibacterium paragallinarum serotype C….min 7log10 CFU before inactivation	The vaccine is recommended for the breeder and laying type chicken flocks against infectious coryza caused by Avibacterium paragallinarum infection in order to reduce clinical signs and lesions of the disease	**Contraindication**: No contraindications are known. **Side Effect**: Vaccination does not cause systemic reactions or significant reactions at the site of injection	HUNGARY		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
03	Green Cross Veterinary Products Co. Ltd., Korea (ACI Ltd.)	a) Linpeccin WSP 75gm, 100gm, 150gm, 500gm &, 1kg Lincomycin hydrochloride 222g(activity)+ Spectinomycin sulfate 22g(activity)+Glucose q.s	For the prevention and treatment of CRD, CCRD, colibacillosis, staphylococcosis	**Contraindication**: Avoid mixing with any other drugs **Side effect**: Can cause gastrointestinal disorders in case of using in the undirected animals.	KOREA		c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv nj
04	Biomune Company, USA (ACI Ltd.)	a) Cevac Salmune Tek Vaccine 1000 doses (500ml) Salmonella enteritidis, strain 038-90…at least 1.00 OD600/ml per dose through expiration+ Salmonella kentucky, strain 351-06…at least 1.00 OD600/ml per dose through expiration+ Salmonella typhimurium, strain 076-94…at least 1.00 OD600/ml per dose through expiration	For immunization of chickens to aid in the reduction of SE colonization of internal organs, intestines and reproductive tract, ST colonization in the internal organs and intestines, SK colonization in the intestines and SH colonization in the internal organs and reproductive tract.	**Contraindication**: No contraindications are known. **Side Effect**: No side effects are known.	USA		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	Jl‡ai bvg I †Rvbv‡iK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	‡UKwbK`vj mve-Kvgvwi 63 Zg mfvi wm×vš	mfvi wm×vš
05	Unibiotech Co., Ltd. Korea (ACI Ltd.)	a) Sulfa Forte-4 Injectable solution 10ml, 20ml, 30ml, 50ml & 100ml Trimethoprim 40mg+Sulfathiazole 40mg+Sulfadiazine 60mg+sulfamerazine 100mg+Lidocaine hydrochloride 1mg/ml	For treatment and prevention of infectious of the respiratory, urogenital tract, gastro-intestinal tract caused by sulfonamide sensitive bacteria.	**Contraindication**: No contraindications are known. **Side Effect**: No side effects are known.	KOREA		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		b) Ferrivit Injectable solution 10ml, 20ml, 50ml, 100ml & 200ml Iron dextran 100mg+Vitamin A 10000IU+Vitamin D3 1000IU+Vitamin E 10mg/ml	For treatment and prevention of iron deficiency anemia and vitamin A,D3,E deficiency.	**Contraindication**: No contraindications are known. **Side Effect**: No side effects are known.	KOREA		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		c) Uni-Melen Water Soluble Powder 500gm, 1kg, 5kg, 10kg and 20kg Melengestrol Acetate 220mg/kg	For restrain estrus, improve gain rate and feed efficiency.	**Contraindication**: Wear gloves & mask when handling the premix. **Side Effect**: No side effects are known.	KOREA		c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj
06	Eagle Vet. Tech Co., Ltd. Korea (ACI Ltd.)	a) Bupaquone Injection Injectable solution 20ml, 50ml, 100ml, 200ml & 500ml Bupavaquone 50mg+Myglyo1840 350mg+sorbitan sesquioleate 100mg+N-Methyl-2-pyrrolidone 500mg/ml	For treatment and prevention of several bovine protozoa infection including Theileria, east coast fever, Corridor disease, Tropical theileriosis.	**Contraindication**: Not for the cows producing milk. **Side Effect**: Not for the animals having anaphylaxis with the drug.	KOREA		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		b) Hepavita Injection Injectable solution 50ml & 100ml Taurine 25mg +Thiamine hydrochloride 5mg + Riboflavin sodium phosphate 1.333mg + Pyridoxine hydrochloride 0.5mg + Cyanocobalamin 1.5µg + Ascorbic acid 10mg+Nicotinamide 10mg + dl-methionine 15mg/ml	For the detoxication of various intoxication and the prevention of liver malfunction, adverse reactions and intoxication of chemicals.	**Contraindication**: No contraindications are known. **Side Effect**: No side effects are known.	KOREA		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †R¡bwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	‡UK¡bK¨vj mve-K¡gvUi 63 Zg mfvi wm×vš	mfvi wm×vš
07	Zoetis Inc., 333 Portage Street, Kalamazoo, Michigan 49007 USA (previously doing business as Alpharma LLC., A Division of Pfizer Inc.), 1301 lowa Avenue, Longmont, Colorado, 80501, USA. **[AG-NOBLE (BANGLADESH) LIMITED.** Lal Bhaban (7th Floor), 18 Rajuk Avenue, Motijheel C/A, Dhaka-1000, Bangladesh.]	a) **BMD® Soluble 50%** Soluble bacitracin methylene disalicylate (50 gms bacitracin activity) via Drinking water administration. For veterinary use. **Antibiotic**	Used for the prevention and control of necrotic enteritis caused by Clostridium perfringens in broiler and replacement chickens.	Contra-indication & Side-effect : None	USA		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
08	J.N. Jorenku, Teglavaerksvej 11, DK 4733 Tappernoji, Denmark **Univet Limited.** H # 01, Road # 10/A, Nikunja-1, Khilkhet, Dhaka-1229.	a) Staldren Chloramine T EP 0.30% **Disinfectant**	Staldren is a hygiene solution in powder form, which has very broad effect against dampness, smell, bacterial and fungal spores. Use at a rate of 50/100gm per m² once or twice a week, more often if envernment conditions dictate or disease is detected	No warnings for this product. As the product has been tested for oral and dermal toxicity with great results. Furthere more staldren only contains 0.3% Chloramine T. Which is a very small amount.	Denmark		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
09	Seul Vet Pharma Co. Ltd, Korea. 81, Youngchon-Gil, Meangdong-Myun Eumsung-Gun, Chungbuk, Korea. **Univet Limited.** H # 01, Road # 10/A, Nikunja-1, Khilkhet, Dhaka-1229.	a) Colicide Solution Colistin Sulphate USP 25%	Prevention and Treatment of Colibacilosis, Cronic respiratory disease by E-Coli and complex infection. 01.Chick : Prevention and treatment of Colibacilosis and omphalitis by gram negative bacteria 2. Chicken: Prevention and treatment of Chronic respiratory disease by E.coli and complex infection. 3.Rabit : Respiratory infection (Pasteurellosis)	Adverse reactions to Colistimethate have been noted in 20% of pt given the drug. They are generally reversible (Goodman,L.S and A Gilman. The pharmacological Basis Of therapeutics. 5th ed. Newyork. Not indicated for ifections caused by proteus or neisseria species,/Sodium colistomethate (McEvoy, G.k ed.American Hospital Formulary service –Drug Information 97. Bethesada, MD: American socity of Health-System pharmacists.	Korea		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	Jl‡ai bvg I †R¤^bwiK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	‡UK¤^bK`vj mve-K¤^gvUi 63 Zg mfvi wm×vš	mfvi wm×vš
10.	Andres Pintaluba S.A Poligono Industrial Agro-Reus/C Prudenci Bertrana, 5, 43206 reus Spain **Univet Limited.** H # 01, Road # 10/A, Nikunja-1, Khilkhet, Dhaka-1229.	a) APSA VITA-C 250 Ascorbic Acid 25%	Apsa Vita – C 250 is a powerful antioxidant, which helps to strengthen blood vessels (Prevents blood vessel fragility) and body muscles to improve reproductive efficiency. It also suports the immune system in fighting infectious disease and parasites. Antioxidant activity, by the stabilization of unsaturated fatty acids, prevent alterations to normal cell functions. Apsa vita – c 250 also improves blood coagulation and helps to maintain healthy liver, heart and muscles. Apsa Vita-C 250 is essential for tissue formation and reduces susceptibility to stress.	As the main component of APSA ViTA – C 250 is vitamin –C (Ascorbic Acid) and is generally a non-toxixic substance, any case of toxicity (hepervitaminosis C) has been reported.	Spain		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
11	Komipharm International Co. Ltd., Korea (Rafique Medicine, College Road, Inshurdi, Pabna)	a) Pro-Vac IBD Plus Vaccine Per Unit dose : Infectious Bursal Disease Virus (K7 Strain) Min 102.5EID50 Freeze Drying protectant (TPGG) 20%	For the prevention against IBD (Avian Infectious Bursal Disease: Gamboro) in chicken	Contra Indication : Do not administer this product to following ones : - Those with fever or serious nutritional lesion. - Those with ferver infectious disease, parasite infection or stress. -Those with hypersensitivity to this kind of vaccine. -If have any abnormalities finding, do not use this product Side-effect : After vaccination, it may occur such as fever, behavior anxiety, lack of vigor, reduced feed intake, reduced egg production, hypersensitivity like swelling and inflammation at the injection site, if hypersensitivity occur, treat properly with veterinarian.	Korea		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		b) Amoclan Injection Amoxicillin Trihydrate 140 mg + Potassium Clavulanate 35 mg/1ml	For the prevention and treatment of diseases of small & big animals by gram positive bacillus and gram negative bacillus.	Contra-indications : If mixed with other product containing magnesium, aluminium and calcium ion, in vivo absorption ratio can be decreased. When administered together with theophylline and caffeine, it can increase blood concentration of theophylline and caffine. Side-effect : Over dosage may cause vomiting and lower intak.	Korea		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	Jl‡ai bvg I †Rvlbv iK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	‡UKwbK`vj mve-Kvgvwi 63 Zg mfvi wm×vš	mfvi wm×vš
	Komipharm International Co. Ltd., Korea (Rafique Medicine, College Road, Inshurdi, Pabna)	c) Komi Linco 4.4 Powder Lincomycin Hydrochloride USP 44 gm/Kg	It is used for the treatment against CRD, Prevention against enteritis, improvement in rate gain, improvement of feed efficiency and coloring effect.	Contra-indications : Do not use on animal had shock and hypersensitive reactions, hepathopathy and renal failure Side-effect : Lincomycin was toxic in mice and rats when administered per enterally and was practically non toxic after oral administration. Lincomycin was toxic to rebbits by all routes of administration	Korea		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		d) Komiquindox Powder Olaquindox 100 gm + Calcium Carbonate 300 gm/Kg	Help growth stimulating poultry and feed efficiency. Promote health & growth. Use for the treatment of diarrhea in both poultry and Livestock. Prevent infection from the bacteria, fungi & virus. Gives better egg production and improves eggshell weight. Energy provider.	Contra-indications : N/A Side-effect : N/A	Korea		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
12.	Laboratorios Hipra S.A., Spain (Nasco Agro Products)	a) Avisan Secure 1000 dose/bottle Inactivated Salmonella enteritidis PT4……MAT≥1/13 Inactivated Salmonella typhimurium DT104……MAT≥1/40* /dose(0.5ml) *title obtained by Microagglutination technique on plates after inoculation of the vaccine in SPF chicks.	To prevent Salmonella enteritidis and Salmonella typhimurium	**Contraindications**: Not to use during egg production **Side effects:** Moderate depression in 7% of birds with a maximum duration od 2 days.	Spain		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		b) Hipraviar-ILT 1000 dose/vial Live Avian Infectious Laryngotracheitis virus, Strain CHP……10^3 - $10^{3.5}$ EID50 /dose	To prevent Infectious Laryngotracheitis	**Contraindications**: Not to use during lay **Side effects:** No palpable reactions were observed following the injection of one dose of vaccine.	Spain		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †Rvbv‡iK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	‡UKwbK`vj mve-Kvgvwi 63 Zg mfvi wm×vš	mfvi wm×vš
13	LABORATORIOS OVEJERO S.A. . Ctra. Leon-Vilecha, 30, Leon, Spain. (Eskayef Bangladesh Ltd.)	a) INMUGAL I. B H120 Avian infectious bronchitis virus attenuated H-120 Massachusetts strains ≥10^5 D	Active Immunization against Infectious Bronchitis of Poultry	No Contraindication is known & Post-vaccine reaction is light, both in prime-vaccinations and in emergency vaccination. It depends on antibody rate. It can cause a total or partial egg-laying decrease in hens' lack of antibodies. It can also produce respiratory symptoms like coughing, sneezing and tracheal rales, wet eyes, and dyspnea. Facial or head swelling is seen occasionally.	Spain	New	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj
		b) INMUGAL V.P. HITCHNER B-1 Active virus of Newcastle disease, attenuated strain Hitchner B1 ≥10^6 $EID_{50/Dose}$	Active immunisation of chickens and adult hens against Newcastle disease. It may be also use for primary and emergency vaccination from one day old.	Do not vaccinate ill animals. & Post-vaccine reaction is mild, both in primary and emergency vaccinations. Slight respiratory disturbances and fall in egg production may occur some days after vaccination in case of animals without antibodies.	Spain	New	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj
		c) INMUGAL NEWCASTLE AVIAR Inactivated viruses against Newcastle disease, Ulster 2C strain Eur. Phar ≥$50DP_{50}$/Dose	For active immunisation against Newcastle Disease of poultry.	No Contraindication is known & In healthy birds no clinical reaction to the vaccination is observed. For some weeks after the vaccination, a slight swelling may be observed at the vaccination site. If you notice any serious effect or other effects not mentioned in this leaflet, please inform your veterinary surgeon.	Spain	New	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv †h‡Z cv‡i	c‡qvRb ‡bB wea‡q Av‡e`b bvgÄyK iv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbviK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	LABORATORIOS OVEJERO S.A. . Ctra. Leon-Vilecha, 30, Leon, Spain. (Eskayef Bangladesh Ltd.)	d) MASTIVAC Each 5ml contains: Streptococcus agalactiae inactivated Eur. Ph P.R≥1 + , Streptococcus dysgalactiae Eur. Ph P.R≥1 + Streptococcus uberis inactivated Eur. Ph P.R≥1+ Streptococcus pyogenes inactivated Eur. Ph P.R≥1+ Staphylococcus aureus inactivated Eur. Ph P.R≥1 Arcanobacterium pyogenes inactivated Eur. Ph P.R≥1 + Escherichia coli (strains:Bov-10, Bov-15 and Suis) inactivated Eur. Ph P.R≥1 + Escherichia coli strain J5 inactivated Eur. Ph P.R≥1	For the active immunization against clinical and subclinical mammitis of bovine cattle cause by the following microorganisms: Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus uberis, Streptococcus pyogenes, Staphylococcus aureus, Arcanobacterium pyogenes and Escherichia coli. Reduction of the problems of mammitis and decrease of the subclinical mammitis. The immunity appears at 8-10 days of the application of the second dose. The duration of the immunity is at least 6 months.	Do not vaccinate weak or sick animals & No Side effect	Spain	New	Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
14	Merial, France [Advance animal science Co. ltd.]	a) Gallimune 208 ND+Flu H9 M.E. Vaccine The vaccine contains an inactivated H9N2 serotype of Avian Influenza virus, an inactivated Newcastle disease virus, Ulster 2C strain, a preservative, and an oil excipient.	Preventive vaccination of Poultry against Avian Influenza (H9N2) and Newcastle disease.	**Contraindications:** None **Side Effects:** Vaccination with this vaccine is safe and satisfactory when as recommended hereby.	France		c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB wea|q Av‡e`b bvgÄyi Kiv nj
		b) GUMBOPEST Injection Virus Inactive de la Maladie de Gumboro, Souche VNJO….5 $DP50^1$ Virus Inactive de la Maladie de Newcastle, Souche ULSTER ….50$DP50^1$ Inactivated Gumboro disease virus, Strain VNJO….5 $PD50^1$ Inactivated Newcastle disease virus, Strain ULSTER ….50$PD50^1$	For prevention against Gumboro, and	**Contraindications:** Injection via subcutaneous/Intramascular route at the rate of 0.3ml per dose is perfectly safe. **Side Effects:** No reaction could be detected after vaccination.	France		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbviK bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
15	Merial Inc, USA [Advance animal science Co. ltd.]	a) BDA BLEN Vaccine Each Dose of vaccine contains the following through expirations: Infectious Bursal Disease Virus, 2512 strain, at least……100 EID_{50} Bursal Disease Virul Antiserum, at least……24Units Gentamicin……0.2mcg	For the prevention of Bursal disease.	**Contraindications:** None **Side Effects:** Vaccination with BDA Blen vaccine was determined to be afe in subcutaneous injection of chickens at one day of age or in vivo vaccination of 18 to 19 days old embryonated eggs.	USA		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
16	Merial Italia S.p.A., Italy [Advance animal science Co. ltd.]	a) BIO CHOLERA Injectable Emulsion Each 0.5ml dose contains: Pasteurella multocida, serotype A-1 inactivated, with minimum titer 7 log2 GMT U.ELISA Pasteurella multocida, serotype A-3 inactivated, with minimum titer 7 log2 GMT U.ELISA Pasteurella multocida, serotype A-4 inactivated, with minimum titer 7 log2 GMT U.ELISA	For prevention against Pasterella multocida(Fowl Cholera) Infection in poultry	**Contraindications:** In case of accindental injection to man urgent medical attention should be taken. **Side Effects:** Local reactions do not occur, if the vaccine is inoculatedproperly but traces of oil may be found for sometimes at injection site.	Italy		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		b) BIO TYPHOID Inactivated Vaccine Each 0.5ml dose contains: Salmonella gallinarum, highly immunogenic strain, inactivated, minimum tire before inactivation 3.5x108 CFU	For prevention against Salmonella Gallinarum infection in Poultry	**Contraindications:** In case of accindental injection to man urgent medical attention should be taken. **Side Effects:** Local reactions do not occur, if the vaccine is inoculatedproperly but traces of oil may be found for sometimes at injection site.	Italy		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
17	Ceva-Phylaxia Veterinary Biolozicals Co. ltd., Hungary [Navana Pharma Ltd.]	a) ITA CORYZA ABC Gel Vaccine A combination of Avibacterium paragallinarum, serotypes A, B and C, homogenized with aluminium hydroxide adjuvant and merthiolate as a preservative.	Recommended for the vaccination of breeder and layer-type chicken flocks, against infectious coryza caused by Avibacterium paregallinarum.	Do not mix the vaccine with other vaccines or drug.	FSC-Hungary		c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv †h‡Z cv‡i	c‡qvRb ‡bB weavq Av‡e`b bvgÄyi Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †R¤^bvi‡K bvg	wb‡`kbv	Contraindication & Side-effect	FSC/CPP	Status (New Molecule/ Existing)	‡UK¤^bK¨vj mve-K¤^gvUi 63 Zg mfvi wm×vš	mfvi wm×vš
18.	Intracare BV, The Netherlands (Bengal Overseas Ltd.)	a) **Intra Hoof-Fit Gel** Viscous Gel 330 ml Jar Cooper Diammonium EDTA In House 214 gm eq. to Copper 40 gm + Zinc Diammonium EDTA In House 207 gm eq. to Zinc 40 gm /1000 gm	Treatment for hoof ailments of animal. Intra Hoof-Fit Gel contains two active ingredients and therefore is a fixed combination. Both components are required, as these components have a different clinical effect and thus provide a two way mechanism for an effective hoof treatment. Zinc is mainly incorporated for its effects on wound repair and copper is mainly incorporated for its antimicrobial properties, while it is also has an effect on wound repair but with a different mechanism of action. This way, Intra Hoof-Fit Gen treatment is based on inhibiting the cause of the disease (bacterial infection) as well as stimulating healing of the large open lesion.	Contraindication: Avoid contact with eyes, When using do not eat, drink or smoke. Side effect: None	The Netherlands		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		b) **Intra Multi-Des GA** Solution 10L & 20L Glutaraldehyde Ph. Eur 125 gm + Alkyldimethylbenzylammonium Chlorides Ph. Eur 150 gm + Didecyldimenthylamonium Chloride In House 100 gm /1000 ml **Biocide product (Disinfectant)**	Intra Multi-Des GA is used as disinfectant. Intra Multi-Des GA can be used in a variety of application for disinfecting purpose (bacteria, yeasts, fungi and viruses excluding polio). IT can used in Animal houses and material, animal transport and materials, storage and processing rooms for feed and food, food transport, boots and wheels via dipping baths.	Contraindication: Flammable material, May be corrosive to metals, Harmful if swallowed, Toxic to aquatic life, Causes severe skin burns. Side effect: May cause respiratory irritation, May cause an allergic skin reaction.	The Netherlands		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj
		c) **Intra Hydrocare** Solution 1L, 5L, 10L & 20L Hydrogen peroxide Ph. Eur. 590 gm /1000 ml **Biocide product (Disinfectant)**	Hydrogen peroxide functions as oxidizer of organic material. Intra Hydrocare is an oxidizing agent for removing organic pollution and manganese deposits in drinking water systems of the intensive life stock area. It can be used in both presence or absence of animal.	Contraindication: Activation with UV, metals, alkali, organic materials leads almost always to an uncontrolled and complete decomposition of the hydrogen peroxide. Therefore the use of Intra Hydrocare can never be done in combination with any other additives, like medicines, vaccines or organic acids etc. Side effect: Intra Hydrocare can react strong with reducing agents.	The Netherlands		Abyjgv`b Kiv †h‡Z cv‡i	Abyjgv`b Kiv nj

2.7 Proposed Product for Local Manufacture (Medical Devices Others)

bs	c¯ZKvi‡Ki bvg	Jl‡ai bvg I †Rvwbvi‡K bvg	wb‡`kbv	Contraindication & Side-effect	‡UKwbK¨vj mve-Kvgvwi 63 Zg mfvi wm×vš	mfvi wm×vš
01.	Incepta Pharmaceuticals Ltd.	a) Hydrocolloid Wound dressing Gelatin (Bovanie source) USP/BP/EP 1.490625 Kg/Batch of 1000 pices of Dermatec (Pack size 15 cm x 15 cm, 5 Nos)	It is indicated for bandage the affected area of body in burning case	**Contraindications:** N/A **Side Effects:** N/A	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj	
		b) Typhokit Antigen In House 9µg + Gold conjugated solution/antibody In House 3 µg + Rabbit Antigoat IgG BP 0.156 µg + Nitrocellulose membrane BP 7cm(L), 3mm (W) + Absorbent Pad BP 3cm(L), 3mm (W) + Sample Pad BP 2.8cm(L), 3mm (W) + Gold Conjugated Pad BP 3cm(L), 3mm (W) + Masking pad BP 2cm(L), 3mm (W)/Kit	Typhokit is used for specific and sensitive diagnosis of typhoid and paratyphoid (without any cross reactivity with other diseases causing enteric fever) from the blood sample collected or received from patient	**Contraindications:** Do not test this strip with other diluents beyond those given in the box. The sample processing steps must be performed on Bio safety cabinet to avoid contamination. **Side Effects:** N/A	Abyôgv`b Kiv †h‡Z cv‡i	Abyôgv`b Kiv nj	

2.8 Proposed Product for Import (Medical Devices Others)

bs	c¯ZKvi‡Ki bvg	Jl‡ai bvg I †Rvbv‡iK bvg		wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-Kvgv‡Ui 63 Zg mfvi wm×vš	mfvi wm×vš
01.	Medtronic, Inc. 710 Medtronic Park Way, Minneapolis, MN 55432, USA Bangladesh Branch Office: Level –06, Shanta Western Tower 186, Bir Uttam Mir Sawkat Road Tejgaon Industrial Area, Dhaka – 1208	**a)**	Medtronic Open Pivot Heart Valve **Relevant model of the Device:** Valve Standard Series - Model 500FA (Aortic) Heart Valve-Aortic & Mitral-Mechanical Type	Intended for use as a replacement valve in patients with diseased, damaged or malfunctioning Aortic /Mitral heart valves. The device may also be used to replace a previously implanted prosthetic heart valve	**Contraindications**: Contraindicated in patients unable to tolerate anticoagulation therapy. **Side Effect:** None	USA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj
		b)	**Brand Name:** Medtronic Open Pivot Heart Valve **Relevant model of the Device:** Valve AP Series - Model 501DA (Aortic) Heart Valve-Aortic & Mitral-Mechanical Type	Intended for use as a replacement valve in patients with diseased, damaged or malfunctioning Aortic /Mitral heart valves. The device may also be used to replace a previously implanted prosthetic heart valve	**Contraindications**: Contraindicated in patients unable to tolerate anticoagulation therapy. **Side Effect:** None	USA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj
		c)	**Brand Name:** Medtronic Open Pivot Heart Valve **Relevant model of the Device:** Valve APex Series - Model 503DA (Aortic) Heart Valve-Aortic & Mitral-Mechanical Type	Intended for use as a replacement valve in patients with diseased, damaged or malfunctioning Aortic /Mitral heart valves. The device may also be used to replace a previously implanted prosthetic heart valve	**Contraindications**: Contraindicated in patients unable to tolerate anticoagulation therapy. **Side Effect:** None	USA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj
		d)	**Brand Name:** Medtronic Open Pivot Heart Valve **Relevant model of the Device:** Valve AP360 Series - Model 505DA (Aortic) Heart Valve-Aortic & Mitral-Mechanical Type	Intended for use as a replacement valve in patients with diseased, damaged or malfunctioning Aortic /Mitral heart valves. The device may also be used to replace a previously implanted prosthetic heart valve	**Contraindications**: Contraindicated in patients unable to tolerate anticoagulation therapy. **Side Effect:** None	USA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbvwiK bvg		wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK`vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Medtronic, Inc. 710 Medtronic Park Way, Minneapolis, MN 55432, USA Bangladesh Branch Office: Level –06, Shanta Western Tower 186, Bir Uttam Mir Sawkat Road Tejgaon Industrial Area, Dhaka – 1208	**e)**	**Brand Name:** Medtronic Open Pivot Heart Valve **Relevant model of the Device:** Valve Standard Series - Model 500DM (Mitral) Heart Valve-Aortic & Mitral-Mechanical Type	Intended for use as a replacement valve in patients with diseased, damaged or malfunctioning Aortic /Mitral heart valves. The device may also be used to replace a previously implanted prosthetic heart valve	**Contraindications**: Contraindicated in patients unable to tolerate anticoagulation therapy. **Side Effect:** None	USA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj
		f)	**Brand Name:** Medtronic Open Pivot Heart Valve **Relevant model of the Device:** Valve AP Series - Model 501DM (Mitral) Heart Valve-Aortic & Mitral-Mechanical Type	Intended for use as a replacement valve in patients with diseased, damaged or malfunctioning Aortic /Mitral heart valves. The device may also be used to replace a previously implanted prosthetic heart valve	**Contraindications**: Contraindicated in patients unable to tolerate anticoagulation therapy. **Side Effect:** None	USA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj
		g)	**Brand Name:** Medtronic Open Pivot Heart Valve **Relevant model of the Device:** Valve AP360 Series – Model 505DM (Mitral) Heart Valve-Aortic & Mitral-Mechanical Type	Intended for use as a replacement valve in patients with diseased, damaged or malfunctioning Aortic /Mitral heart valves. The device may also be used to replace a previously implanted prosthetic heart valve	**Contraindications**: Contraindicated in patients unable to tolerate anticoagulation therapy. **Side Effect:** None	USA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj
		h)	**Brand Name:** Medtronic Open Pivot Aortic Valved Graft **Model of the Device:** Aortic Valved Graft (AVG) – Model 502AG Aortic Valved Graft	Intended for use secondary to a diseased, damaged or malfunctioning aortic valve with aortic aneurysmal or occlusive disease where a replacement valve and replacement or repair of the aorta is required. The device may be used to replace a previously implanted prosthetic heart valve and a conduit.	**Contraindications**: Contraindicated in patients unable to tolerate anticoagulation therapy. The Hamashield Woven Double Velour Vascular Graft is not approved for use as a coronary artery replacement. **Side Effect:** None	USA	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvlbviK bvg		wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK¨vj mve-KvgvUi 63 Zg mfvi wm×vš	mfvi wm×vš
02	Zhejian Gongdong Medical Technology Co. Ltd., China [Glory International, Noakhali]	**a)**	Disposable Vacuum Blood Collection system Blood Collection system	Used for blood collection.	**Contraindications and Side Effects:** N/A	Germany (EC Certificate)	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj
03	Laiwn Yaohua Pharmaceuticals Packaging Co. Ltd., China [RA Traders, 135 Nawbpur Road, Dhaka]	**a)**	Disposable Vacuum Blood Collection Tube and Needle Disposable Vacuum Blood Collection Tube and Needle	Use with needle drawing blood sample.	**Contraindications and Side Effects:** N/A	China	c`wUi Avwe`b bvgÄyK iv †h‡Z cv‡i	c`wUi Avwe`b bvgÄyK iv nj
04	BARD SDN BHD, Malaysia [Lilac (Private) Ltd., 72, New Elephant Road, Dhaka]	**a)**	Bardia Foley Catheter Urinary Catheter	Drain urine from urinary Bladder	**Contraindications: and Side Effects:** N/A	TGA (Australia)	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj
		b)	Bardex Foley Catheter Urinary Catheter	Drain urine from urinary Bladder	**Contraindications: and Side Effects:** N/A	TGA (Australia)	Abygv`b Kiv †h‡Z cv‡i	Abygv`b Kiv nj

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †Rvbv‡iK bvg		wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK¨vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
05	FARMA-DERMA s.r.l, Via Dei Bersaglieri, 10, 400100 Sala Bolgnese, Bologna, Italy. **MAH:** Proximo Health Solucion	a)	Aquafilling Faceline1mg.Injection Cation copolyamide-2%, 0.9% physiologic solution of sodium chloride-98%.	Hydrophilic gel is recommended for application under the following indications: 1. Contour correction of facial soft tissues; 2. Removal of age-related changes of face. 3. Change of lips form and volume. 4. Removal of asymmetry of facial soft tissues; 5. Removal of post traumatic, post surgical, congenital malformations and defects of facial soft tissues. 6. Removal of atrophic changes of soft tissues in face zone.	**Contraindication:** Do not use the product if the package is damaged or the sterility of material is broken. Do not perform the procedure under the following conditions, if a person: -is pregnant or breast feeding; -has poor mental health; -currently takes anticoagulants or aspirin; -has a skin infection or inflammatory disease; -has permanent implants; -has acute contagious disease of a specific and nonspecific etiology; -has chronic contagious diseases in sustained remission stage or recrudescence; -has intolerability or allergy to medicines; -has vessels diseases of different etiology; **Side effects:** The most common adverse events observed during the application period of Aquafilling are bruising, edema, redness, itching, and pain. In case of infiltrations formation n in the soft tissues the intensive local and general antibiotic therapy is recommended during 5-7 days, thus pain is arrested.	Czech Republic	c`wUi Av‡e`‡bi wel‡q gZvgZ c`v‡bi Rb¨ wb¤ewYZ we‡kl‡Ái mgš‡q GKwU KwgwU MVb Kiv nj- (1) Aa¨vcK Ww. †gvt BmgvBj Lvb, dvgv‡Kvjv‡R wefvM, XvKv †gvW‡Kj K‡jR- mfvcwZ; (2) Aa¨vcK Ww. †gvt RvKxi †nv‡mb, wefvMxq cavb, Wvgv‡Uvjv‡R wefvM, m¨vi mvjgvwn †gvW‡Ki K‡jR, XvKv-m`m¨; (3) Rbve mykgvi iÄb †Nvl, cwZwbwa, evsjv‡`k dvgwmDwUK¨vj B‡¤úvUvm G‡mvwm‡qkb-m`m¨ (4) Rbve Gg †gvQv‡ïK †nv‡mb, cwZwbwa, evsjv‡`k dv‡gmx KvDwÝj, XvKv-m`m¨; (5) Rbve †gvt †Mvjvg wKewiqv, cwiPvjK, Jla ckvmb Awa`ßi- m`m¨ mwPe| D³ KwgwUi gZvg‡Zi wfwË‡Z cieZx‡Z wm×vš MnY Kiv n‡e|	‡UKwbK¨vj mve-KwgwUi mycwik Abyhvqx `b Kiv nj|

bs	c¯ZKvi‡Ki bvg	Jl‡ai bvg I †Rvbv‡iK bvg		wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK¨vj mve-K‡gwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	FARMA-DERMA s.r.l, Via Dei Bersaglieri, 10, 400100 Sala Bolgnese, Bologna, Italy. **MAH:** Proximo Health Solucion	b)	Aquafilling Body line 100gm Injection Cation copolyamide-2%, 0.9% physiologic solution of sodium chloride-98%.	Hydrophilic gel is recommended for application under the following indications 1. Contour correction of body soft tissues; 2. Removal of mammary aplasia; 3. Removal of mammary hypomastia; 4. Removal of mammary hypomastia accompanied by glandulous; 5. Removal of asymmetry of soft breast tissues; 6. Removal of deformities of the breast tissues; 7. Improvement of breast volume and shape; 8. Buttocks augmentation.	**Contraindications:** Do not use the product if the package is damaged or the sterility of material is broken. Do not perform the procedure under the following conditions, if a person: -is younger than 18 years; -has poor mental health; -has apparent ptois(type 2-3); -has mastopathy; Is within 9 months after delivery: -has very small distance from the tear to the submammary fold; -has blood coagulation troubles, menstruation abnormalities; -currently takes anticoagulants or aspirin; -has a skin infection or inflammatory disease; -has permanent implants; -has acute contagious disease of a specific and nonspecific etiology; -has chronic contagious diseases in sustained remission stage or recrudescence; -has intolerability or allergy to medicines; -has vessels diseases of different etiology; -has severe general somatic diseases, oncology. **Side effects**: The most common adverse events observed during the application period of Aquafilling are bruising, edema, redness, itching, and pain. In case of infiltrations formation n in the soft tissues the intensive local and general antibiotic therapy is recommended during 5-7 days, thus pain is arrested.	Czech Republic	c`wUi Av‡e`‡bi wel‡q gZvgZ c`v‡bi Rb¨ wb¤ewYZ we‡kl‡Ái mgš‡q GKwU KwgwU MVb Kiv nj- (1) Aa¨vcK Ww. †gvt BmgvBj Lvb, dvgv‡Kvjv‡R wefvM, XvKv †gvW‡Kj K‡jR- mfvcwZ; (2) Aa¨vcK Ww. †gvt RvKxi †nv‡mb, wefvMxq cavb, Wvgv‡Uvjv‡R wefvM, m¨vi mvjgvwn †gvW‡Ki K‡jR, XvKv-m`m¨; (3) Rbve mykgvi iÄb †Nvl, cwZwbwa, evsjv‡`k dvgwmDwUK¨vj B‡¤úvUvm G‡mvwm‡qkb-m`m¨ (4) Rbve Gg †gvQv‡ïK †nv‡mb, cwZwbwa, evsjv‡`k dv‡gmx KvDwÝj, XvKv-m`m¨; (5) Rbve †gvt †Mvjvg wKewiqv, cwiPvjK, Jla ckvmb Awa`ßi- m`m¨ mwPe| D³ KwgwUi gZvg‡Zi wfwË‡Z cieZx‡Z wm×vš MnY Kiv n‡e|	‡UKwbK¨vj mve-K‡gwUi mycwik Abyhvqx`b Kiv nj|

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbvwiK bvg		wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK¨vj mve-Kvgvwi 63 Zg mfvi wm×vš	mfvi wm×vš
	FARMA-DERMA s.r.l, Via Dei Bersaglieri, 10, 400100 Sala Bolgnese, Bologna, Italy. **MAH:** Proximo Health Solucion	c)	Reconval B6 Cream purified water, olive oil, glyceryl stearate, vaseline, urea, cholesterol, propylene glycol, allantoin, cetyl alcohol, phenoxyethanol, vitamin B6, Stearate(75) oe, beeswax, cetyl palmitate, triethanolamine, 1,2 hexanedyol, caprylyl glycol, cetil(20)oe, stearil(20)oe, acrylates/C 10-30 alkyl acrylate crosspolymer, pentaerithrityl tetra-di-butyl hydroxyhydrocinnamate, ethylhexylglycerin, sodium hydroxide.	Reconval B6 is recommended for application under the following indications: - Inflamed skin (i.e. Hand Foot syndrome) and - skin reactions during and after dermatological treatment& oncological treatment	**Contraindication:** Do not use the product if the package is damaged . Do not use in cases of established or suspected hypersensitivity for one or more than one components present in the product It is suggested to consult a doctor before use, particularly if you are treating the skin with other topical products. In case of undesired reactions suspend the treatment and consult a doctor. **Side Effects**:N/A	Slovenia, EU.	*H*	*H*
		d)	Reconval K1 Cream. Dimineralized water,olive oil, glyceryl stearate, petrolatum, urea, cholesterol, propylene glycol, allantoin, cetyl alcohol, phenoxyethanol, stearate (75)oe, beeswax, cetyl palmitate, cetyl(20)oe, stearyl(20)oe, acrylates/C10-30 alkyl acrylate crosspolymer, polyperfluromethylisopropyl ether, pentaerithrityl tetra-di-t-butyl hydroxyhydrocinnamate, vitamin k1, ethylhexylglycerin, triethanolamine.	Reconval K1 is recommended for application under the following indications: 1. Irritated skin(for example after drug treatment); 2. Skin with acne; 3. Protective Cream for restoring the physiological conditions of the skin damaged by external and chemical factors;	**Contraindication:** Do not use the product if the package is damaged or the sterility of material is broken. Do not perform the procedure under the following conditions, if a person: -is younger than 18 years; -has poor mental health; -has apparent ptois(type 2-3); -has mastopathy; Is within 9 months after delivery: -has very small distance from the tear to the submammary fold; -has blood coagulation troubles, menstruation abnormalities; -currently takes anticoagulants or aspirin; -has a skin infection or inflammatory disease; -has permanent implants; -has acute contagious disease of a specific and nonspecific etiology; -has chronic contagious diseases in sustained remission stage or recrudescence; -has intolerability or allergy to medicines; -has vessels diseases of different etiology; -has severe general somatic diseases, oncology. **Side effect:** N/A	Slovenia, EU	*H*	*H*

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbvwiK bvg		wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK¨vj mve-KwgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	FARMA-DERMA s.r.l, Via Dei Bersaglieri, 10, 400100 Sala Bolgnese, Bologna, Italy. **MAH:** Proximo Health Solucion	e)	Cicatridina Cream Hyaluronic acid sodium salt, water, liquid paraffin, cetyl-stearyl alcohol, sweet almond oil, polyoxyethylene (2) steryl ether, polyoxyethylene(21) steryl ether, glycerine, sorbitol, silicone oil, chlorhexidine digluconate, imidazolidinyl urea, EDTA bisodium salt, BHT.	Adjuvant treatment of reparative process in the case of: -Irritations and reddenings -After peeling interventions, epilation and laser -Superficial wounds: cracks, scratches, abrasions, rashes, first and second degree burns, superficial cuts. -Deep wounds: surgical wounds, decubitus sores and ulcers.	**Contraindication:** Cicatridina cream must not be used in case of individual hypersensitivity to one of the components of the product. In case of pregnancy and breast feeding it is advisable to consult the doctor. **Side effect:** Use of all products for tropical use, especially if prolonged, may cause sensitization. If this occurs, stop treatment and consult a doctor to start suitable therapy.	Bologna,Italy	*H*	*H*
		f)	Cicatridina Suppositories. Hyaluronic acid sodium salt 5mg, cantella asiatica oil extract, Calendula officinalis oil extract, aloe vera oil extract, tea tree essential oil, semi synthetic glycerides, BHT.	Adjuvant treatment of reparative process of the anorectal canal following proctological surgery; internal and external haemorrhoids; proctitis; cryptitis; anal rhagades; fissures: perianal fistulae.	**Contraindication:** Cicatridina Suppositories must not be used in case of individual hypersensitivity to one of the components of the product. In case of pregnancy and breast feeding it is advisable to consult the doctor. **Side effect:** Use of all products for tropical use, especially if prolonged, may cause sensitization. If this occurs, stop treatment and consult a doctor to start suitable therapy.	Bologna, Italy	*H*	*H*
		g)	Cicatridina vaginal ovule Hyaluronic acid sodium salt 5mg, cantella asiatica oil extract, Calendula officinalis oil extract, aloe vera oil extract, tea tree essential oil, semi synthetic glycerides, BHT.	Adjuvant treatment of reparative process in atrophic and dystrophic conditions of the vaginal mucosa. It helps healing after childbirth, in gynecological surgery, in cases of dystrophy resulting from chemotherapy, ionizing radiation vaginal dryness also due to estrogen deficiency**.**	**Contraindication:** Cicatridina vaginal ovules must not be used in case of individual hypersensitivity to one of the components of the product. In case of pregnancy and breast feeding it is advisable to consult the doctor. **Side Effect:** Use of all products for tropical use, especially if prolonged, may cause sensitization. If this occurs, the user has to stop treatment and consult a doctor to start suitable therapy.	Bologna , Italy	*H*	*H*
06.	Devon Innovations Pvt. Ltd., India [Zain International Medical & Surgical Export Import Ltd.)	**a)**	Ureteral Indwelling double pigtail stent/set (DJ Stent) Ureteral Indwelling double pigtail stent/set (DJ Stent) 2.5F to 10F : 8-30 cm	Used for temporary internal drainage from the Ureteropelvic junction to the bladder. Supplied sterile in peel open pouch. Intended for one time use.	Contraindication: None Side Effects: None	India	DbZ mvZwU †`‡ki g‡a¨ †h †Kvb GKwU †`‡ki FSC /KvbvWv-Gi FSC/EC Certificate `wLj m¤c‡ÿ cieZx mfvq we‡ePbv Kiv n‡e|	‡UKwbK¨vj mve-KwgwUi mycwik Abyôv`b Kiv nj|
		b)	Ureteral Catheter Ureteral Catheter 3F to 8F: 70 cm	Used for dilation of the Ureter prior to Ureteroscopy and /or stone manipulation. Supplied sterile in peel open packages. Used with 0.038” guide-wire	Contraindication: None Side Effects: None	India	*H*	*H*

bs	c¯ZKvi‡Ki bvg	JI‡ai bvg I †RvbvwiK bvg		wb‡`kbv	Contraindication & Side-effect	FSC/CPP	‡UKwbK¨vj mve-KvgwUi 63 Zg mfvi wm×vš	mfvi wm×vš
	Devon Innovations Pvt. Ltd., India [Zain International Medical & Surgical Export Import Ltd.)	**c)**	Percutaneous Pigtail Suprapubic Catheter/Set Percutaneous Pigtail Suprapubic Catheter/Set 6F to 16F : 22-30 cm	Used to provide bladder drainage by percutaneous placement of a pigtail catheter. Supplied sterile in peel open package. Intended for one time use	Contraindication: None Side Effects: None	India	DbZ mvZvU †`‡ki g‡a¨ †h †Kvb GKwU †`‡ki FSC/KvbvWv-Gi FSC/EC Certificate `vwLj m¤c‡ÿ cieZx mfvq we‡ePbv Kiv n‡e|	‡UKwbK¨vj mve-KvgwUi mgvwik Abyôgv`b Kiv nj|
		d)	Percutaneous Pigtail Nephrostomy Catheter/Set Percutaneous Pigtail Nephrostomy Catheter/Set 5F to 16F : 30 cm	Sterile tube inserted into the bladder to drain urine	Contraindication: None Side Effects: None	India	H	H
		e)	Dilator Sets Dilator Sets 5F to 16F : 22-70 cm	Used for dilation of the Ureter prior to Ureteroscopy and or stone manipulation.	Contraindication: None Side Effects: None	India	H	H
		f)	Percutaneous Malecot naphrostomy Catheter Percutaneous Malecot naphrostomy Catheter 8F to 30F : 30 cm	Used for temporary or permanent drainage of urine from the kidney by percutaneous placement	Contraindication: None Side Effects: None	India	H	H
		g)	Guidewires Guidewires 0.018 to 0.038 : 150 cm	Urological Product	Contraindication: None Side Effects: None	India	H	H
07.	Sahajanand Medical Technologies Pvt Ltd., India [Zain International Medical & Surgical Export Import Ltd.)	**a)**	Supraflex (Drug Eluting Coronary Stent) Sirolimus eluting polimer free Coronary Stent system	Disposable use for coronary blockage.	Contraindication: None Side Effects: None	India	H	H

2 L) **Paracetamol 500mg + DL Methionine 100mg Combination Tablet** *Gi †iwR‡÷kb ewZj cm‡½ t*

Paracetamol 500mg + DL Methionine 100mg Combination Tablet *c`wU‡Z* Methionine এর পার্শ্ব প্রতিক্রিয়া এবং ঝুকির বিষয়ে বেশ কিছু তথ্য *‡UKwbK¨vi mve-KwgwUi mfvq Dc¯wcZ n‡j Dcw¯Z m`m¨MY welqwU we¯wiZ Av‡jvPbv K‡ib|*

weMZ 11-08-2011 Zwi‡L Abyôv‡Z Jla wbqšY KwgwUi 240Zg mfvq BNF-61 *†id‡i‡Ýi wfwË‡Z Abyhvqx`Z n‡j I eZgv‡b* BNF-69-*G Ašfy³ †bB| GQvov c`wU* FDA & MHRA *KZ…K Abyhvqx`Z bq|* Combination *c`wU‡Z* Methionine *Gi Dcw¯wZi Kvi‡Y* Cardiovascular complication, carcinogenesis, hepatic encephalopathy, brain damage and acidosis পার্শ্বপ্রতিক্রিয়া *cwijwÿZ nIqvq* Innovator Companies *KZ…K AvšRwZK evRvi nB‡Z cZ¨vnvi Kiv nq| ZvQvov 12 eQ‡i i bx‡Pi †Kvb wkï‡i Rb¨* Methionine Recommended না হওয়ায় এটি অবাধে ব্যবহার ঝুঁকিপূর্ণ। সভায় বিস্তারিত আলোচনাক্রমে নিম্নবর্ণিত *wm×vš Mp,xZ nq|*

‡UKwbK¨vj mve-KwgwUi gZvgZ t Paracetamol 500mg + DL Methionine 100mg Tablet-*Gi †iwR‡÷kb ewZj Kivi myZvwik Kiv nq|*

mfvi Av‡jvPbv t Paracetamol 500mg + DL Methionine 100mg Tablet-*Gi †iwR‡÷kb ewZj* করার বিষয়টি সভায় উপস্থাপন করা হলে, বিস্তারিত আলোচনাক্রমে সর্বসম্মতিক্রমে টেকনিক্যাল সভার *myZvwik envj ivLvi wm×vš Mp,xZ nq|*

mfvi wm×vš t Paracetamol 500mg + DL Methionine 100mg Tablet-*Gi †iwR‡÷kb ewZj Kivi myZvwik Abyhvqx`b Kiv nj|*

3| wewea t

K) **Glimepiride 1 mg+ Metformin BP 500mg Bilayer Tablet** (Glimepiride BP 1mg + Metformin BP 500mg) - *bvgxq JlawU wWwmwm-Gi †UKwbK¨vj mve-KwgwUi 61Zg mfvq c‡qvRb †bB weavq bvgÄyi Kivi myZvwik Kiv nq| wKš Jla wbqšb KwgwUi 243-Gi mfvq JlawUi* Safety, Efficacy & Usefullness *m¤ú‡K (1) Aa¨vcK Rwjj, wefvMxq cavb, G‡ÛvKvB‡bvjwR wefvM, XvKv †gwW‡Kj K‡jR, (2) Aa¨vcK dwi`DÏxb Avn‡g`, †Pqvig¨vb, G‡ÛvKvB‡bvjwR wefvM, weGmGgGgBD, Ges (3) Aa¨vcK nv‡Riv gvnZve, evi‡Wg nwmcvZvj, XvKv Gi gZvgZ MnY Kivi wm×vš Mp,xZ nq|*

we‡klÁMb Zv‡`i wi‡cv‡U Jla wUi Safety, Efficacy & Usefullness m¤ú‡K gj¨vqbceK †iwR‡÷kb c`v‡bi Rb¨ mycwik K‡ib|

mfvi Av‡jvPbv t Glimepiride 1 mg+ Metformin BP 500mg Bilayer Tablet (Glimepiride BP 1mg + Metformin BP 500mg) - bvgxq Jla wUi we‡q we‡klÁM‡bi gZvgZ সভায় বিস্তারিত আলোচনাক্রমে ঔষধটির রেজিস্ট্রেশন অনুমোদনের সিদ্ধান্ত গৃহীত হয়।

mfvi wm×vš t Glimepiride 1 mg+ Metformin BP 500mg Bilayer Tablet (Glimepiride BP 1mg + Metformin BP 500mg) - bvgxq Jla wU Abyôv`b Kiv nj|

L) Pioglitazone I Rosiglitazone ‡R‡bwi‡Ki Jl‡ai †iwR‡÷kb envj ev ewZj we‡q wm×vš MnY cm‡½ t

Jla wbqšb Kwgwi 243Zg mfvi wm×vš †gvZv‡eK MwVZ we‡klÁ Kwgwi Pioglitazone I Rosiglitazone ‡R‡bwi‡Ki Jl‡ai †iwR‡÷kb envj ev ewZj we‡q wm×v‡ši weq‡q 01/07/2015 Zvwi‡L GKwU mfv Abyôv`b nq| mfvq wb¤ewYZ m`m¨e„`` Dcw¯Z wQ‡jb t (‡R¨ôZvi ক্রমানুসারে নয়)

1) †gRi †Rbv‡ij †gvt †gv¯wdRyi ingvb, gnvcwiPvjK, Jla ckvmb Awa`ßi|
2) we‡MwWqvi †Rbv‡ij Avãyjvn Avj dvi¤^K, GKwUs Kbmvj‡U›U wdwRwkqvb †Rbv‡ij, evsjv‡`k AvgW †dv‡mm †gwW‡Kj mwf‡mm, XvKv K¨v›Ub‡g›U, XvKv|
2) অধ্যাপক ফরিদউদ্দিন আহমেদ, চেয়ারম্যান, এন্ডোক্রাইনোলজি বিভাগ, বঙ্গবন্ধু †kL gyRe ‡gwW‡Kj wekwe`¨vjq, XvKv|
3) Aa¨vcK BmgvBj Lvb, Aa¨ÿ, XvKv †gwW‡Kj K‡jR I nvmcvZvj, XvKv|
4) অধ্যাপক জলিল আনসারী, চেয়ারম্যান, এন্ডোক্রাইনোলজি বিভাগ, ঢাকা মেডিকেল কলেজ ও হাসপাতাল, XvKv|
5) অধ্যাপক ফারুক পাঠান, এন্ডোক্রাইনোলজি বিভাগ, বারডেম হাসপাতাল, XvKv|

mfvq ঔষধ দুইটির মাত্রাভেদে কার্যকারিতা এবং বিরূপ প্রতিক্রিয়ার বিষয়ে we¯wiZ Av‡jvPbv †k‡l wb¤wjwLZ wm×vš Mp,xZ nq-

1| Rosiglitazone Gi we`¨gvb `ÿZv gvÎv (2 mg & 4 mg) Gi †iwR‡÷kb ewZ‡ji mgvwik Kiv nq|

2| Pioglitazone Gi SzuK we‡ePbvq 30 mg and 45 mg gvÎv †iwR‡÷kb ewZ‡ji mgvwik Kiv nq Ges KvhKwiZv we‡ePbv K‡i Jl‡ai †gvo‡K jvj Kwj‡Z ¯úóvÿ‡i wb¤ewYZ Z_¨w` g~‡Yi k‡Z 15mg gvÎvi †iwR‡÷kb envj ivLvi mgvwik Kiv nq t

I. Liver Enzyme must be monitored regularly
II. History of heart failure and MI should be varified
III. Incidence of bladder cancer should be varified
IV. Not to be used for elderly patients
V. Not to be used continuously more than one year Ges
VI. Use only by Specialist advise.

mfvi Av‡jvPbv t Pioglitazone I Rosiglitazone ‡R‡bwi‡Ki Jl‡ai †iwR‡÷kb envj ev ewZj wel‡q সিদ্ধান্ত গ্রহণ করার বিষয়টি সভায় উপস্থাপন করা হলে, বিস্তারিত আলোচনাক্রমে we‡klÁ KwgwUi mgvwik envj ivLvi wel‡q mevB GKgZ cKvk K‡ib|

mfvi wm×vš t we‡klÁ KwgwUi mgvwik Abyhvqx `b Kiv nj|

Ab¨ †Kvb Av‡jv‡¯¨ welq bv _vKvq mfvcwZ g‡nv`q Dcw¯Z mKj‡K ab¨ev` Ávcb K‡i mfvi mgvß †NvlYv K‡ib|

‡gRi †Rbv‡ij †gvt ‡gv¯wdRyi ingvb
gnvcwiPvjK
Jla ckvmb Awa`ßi
I
m`m¨-mwPe
Jla wbqšY KwgwU|

‰mq` gbRyi¾j Bmjvg
mwPe
¯v¯¨ I cwievi Kj¨vY gš¿Yvjq
I
mfvcwZ
Jla wbqšY KwgwU|