

গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
ঔষধ প্রশাসন অধিদপ্তর
ঔষধ ভবন, মহাখালী, ঢাকা-১২১২
www.dgda.gov.bd

নং-ডিজিডিএ/এলার্ট-নোটিশ/এমসি-১৬/২০১৯/৭৫২

তারিখঃ ১৭/০৬/২০২১

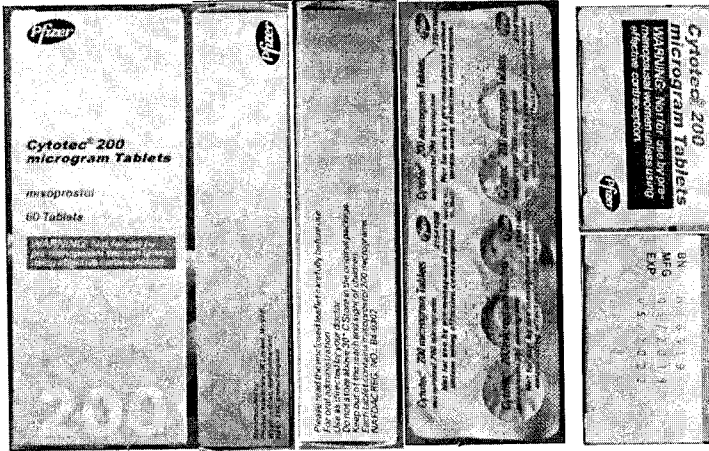
:-অফিস আদেশ:-

ঔষধ প্রশাসন অধিদপ্তরের মাঠ পর্যায়ের সকল কর্মকর্তাদের জানানো যাচ্ছে যে, বিশ্ব স্বাস্থ্য সংস্থা (WHO) সম্প্রতি মেডিক্যাল প্রোডাক্ট এলার্ট N° 3/2021- এ এই মর্মে সতর্ক করেছে যে, PFIZER কর্তৃক উৎপাদিত CYTOTEC 200 microgram tablet এর ব্যাচ B16519 Republic of Congo, Ghana এবং ব্যাচ B14660 Cameroon I Nigeria এর বাজারে নকল (Falsified) হিসাবে পাওয়া গিয়েছে। উল্লেখ্য যে, ল্যাবরেটরিতে বিশ্লেষণ করে দেখা গেছে, B16519 ব্যাচ এর CYTOTEC ঔষধটিতে কোন Active Ingredient এর অস্তিত্ব নাই এবং B14660 ব্যাচ এর ঔষধটিতে মেয়াদউত্তীর্ণের তারিখ নাই।

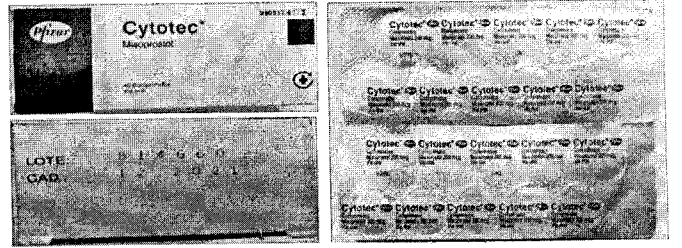
Table 1: Products subject of WHO Medical Product Alert N°3/2021		
Product Name	CYTOTEC 200 microgram tablets	
Stated manufacturer	PFIZER	
Stated active ingredient	misoprostol	
Batch / Lot	B16519	B14660
Mfg. date	05/2019	Not Stated
Exp date	05/2022	12/2021
Identified in	Republic of Congo, Ghana	Cameroon, Nigeria
Packaging language	English	Spanish

Table 2: Photographs of products subject of WHO Medical Product Alert N°3/2021

Falsified CYTOTEC (misoprostol) 200mcg tablets, Batch B16519
Identified in Cameroon, Democratic Republic of Congo, Ghana



Falsified CYTOTEC (misoprostol) 200mcg tablets, Batch number B14660
Identified in Cameroon and Nigeria



এমতাবস্থায়, উপরোল্লিখিত ঔষধটিতে বাজারে পাওয়া গেলে তা বিধি মোতাবেক জব্দ করে প্রয়োজনীয় ব্যবস্থা গ্রহণের জন্য এতদ্বারা নির্দেশ প্রদান করা হলো।

১৭/০৬/২১
মোঃ আসরাফ হোসেন

উপপরিচালক

ঔষধ প্রশাসন অধিদপ্তর, ঢাকা।

ফোনঃ ০২২২২২-৮০৮০৩

Email: dgda.gov@gmail.com

সংযুক্তিঃ ০৩(তিন) পাতা।

Ref. RPQ/REG/ISF/Alert N°3.2021

August 2021

Medical Product Alert N° 3/2021

Falsified CYTOTEK identified in WHO region of Africa

Alert Summary

This WHO Medical Product Alert refers to two batches of falsified CYTOTEK (misoprostol) 200 microgram tablets identified in the WHO Region of Africa and reported to WHO in July 2021. The genuine manufacturer of CYTOTEK has confirmed that the products listed in this Alert are falsified because these products failed laboratory analysis and/or display falsified variable data. These falsified products have been reported at wholesale and patient level in Cameroon, the Democratic Republic of Congo, Ghana and Nigeria.

Misoprostol is listed on the WHO Model List of Essential Medicines. Genuine Cytotec (misoprostol) is indicated for the treatment of duodenal and gastric ulcers. Other uses of misoprostol as recommended by current WHO guidelines include induction of labour and postpartum haemorrhage prophylaxis, treatment of missed and incomplete miscarriages, induction of abortion, and cervical preparation before uterine instrumentation.

The risk to patient health from falsified Cytotec (misoprostol) is ineffective or delayed treatment for all of the above uses and could also be life threatening in some circumstances. It is important to detect and remove any falsified Cytotec (misoprostol) from circulation so as to prevent harm to patients.

The products identified in this Alert are confirmed as falsified on the basis that they deliberately/fraudulently misrepresent their identity, composition or source:

- Batch B16519 – batch number does not correspond to genuine manufactured CYTOTEK. Laboratory analysis of samples has also confirmed the product does not contain any active ingredient and does not comply with specifications;
- Batch 14660 – the expiry date (12/2021) on this product is falsified.

Table 1: Products subject of WHO Medical Product Alert N°3/2021

Product Name	CYTOTEK 200 microgram tablets	
Stated manufacturer	PFIZER	
Stated active ingredient	misoprostol	
Batch / Lot	B16519	B14660
Mfg. date	05/2019	Not Stated
Exp date	05/2022	12/2021
Packaging language	English	Spanish
Identified in	Cameroon, Democratic Republic of Congo, Ghana	Cameroon, Nigeria

For photographs of the above products, please refer to Table 2 on pages 2 & 3 of this Alert.

Advice to regulatory authorities and the public

WHO requests increased vigilance within the supply chains of countries and regions likely to be affected by these falsified products. Increased vigilance should include hospitals, clinics, health centres, wholesalers, distributors, pharmacies and any other suppliers of medical products.

All medical products must be obtained from authorized/licensed suppliers. The products' authenticity and physical condition should be carefully checked. Seek advice from a healthcare professional in case of doubt.

If you are in possession of the above falsified products, please do not use them.

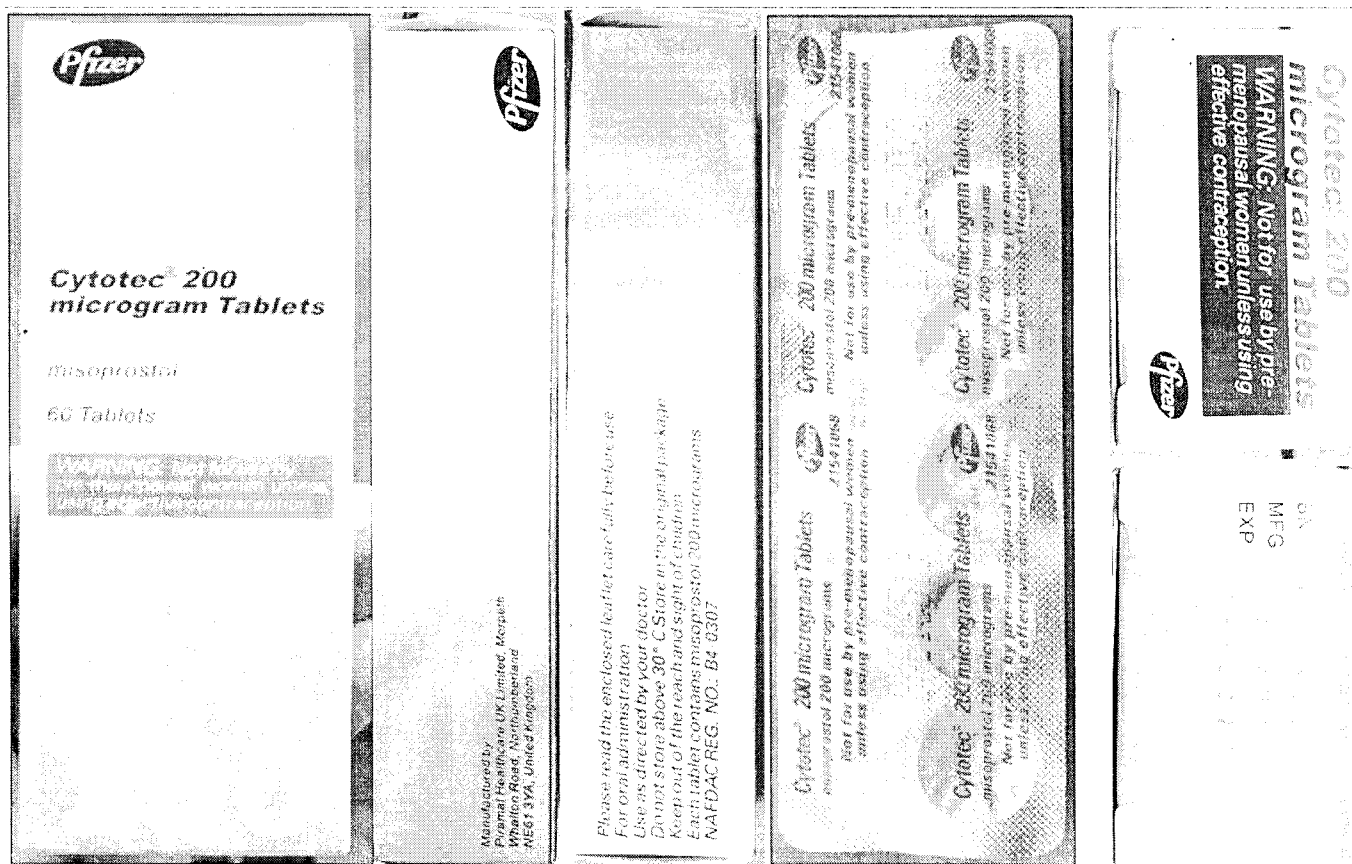
If you have used these products, or you suffered an adverse reaction/event having used these products, you are advised to seek immediate medical advice from a qualified healthcare professional, and to report the incident to the National Regulatory Authorities / National Pharmacovigilance Centre.

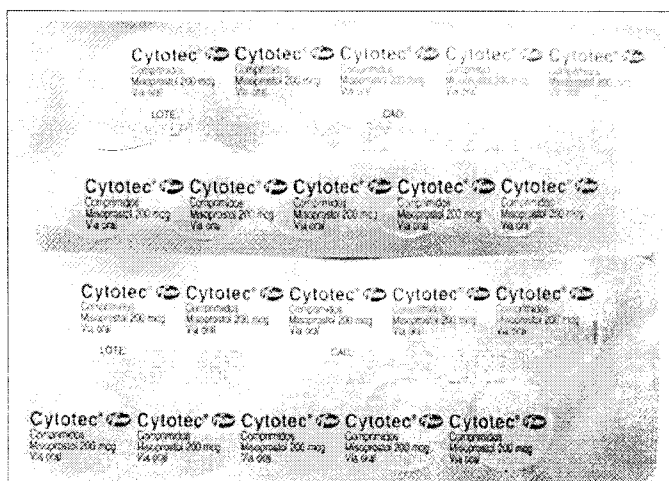
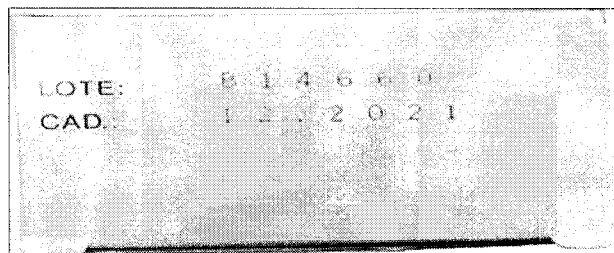
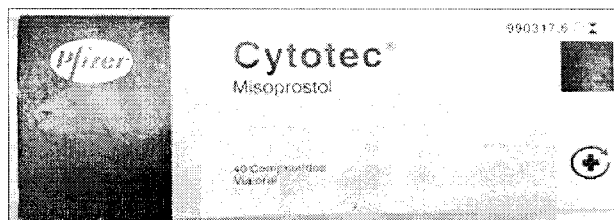
National regulatory / health authorities are advised to immediately notify WHO if these falsified products are discovered in their country. If you have any information concerning the manufacture, distribution, or supply of these products, please contact rapidalert@who.int

Table 2: Photographs of products subject of WHO Medical Product Alert N°3/2021

Falsified CYTOTEC (misoprostol) 200mcg tablets, Batch B16519

identified in Cameroon, Democratic Republic of Congo, Ghana



Falsified CYTOTEC (misoprostol) 200mcg tablets, Batch number B14660**identified in Cameroon and Nigeria****WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products**For more information, please visit our [website](https://www.who.int/rapidalert)Email: rapidalert@who.int