

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

নং-ডিজিডিএ/এলার্ট-নোটিশ/এমসি-১৬/২০১৯/ ২৫৮১৯

তারিখঃ ২৯/১০/২০২১ খ্রিঃ

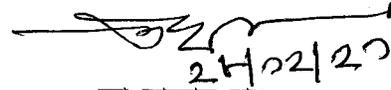
-:অফিস আদেশ:-

ঔষধ প্রশাসন অধিদপ্তরের মাঠ পর্যায়ের সকল কর্মকর্তাদের জানানো যাচ্ছে যে, বিশ্ব স্বাস্থ্য সংস্থা (WHO) সম্প্রতি মেডিক্যাল প্রোডাক্ট এলার্ট N° 8/2021- এ এই মর্মে সতর্ক করেছে যে, Strides Arcolab Ltd. কর্তৃক উৎপাদিত COMBIART Artemether/Lumefantrine Tablets (20/120mg) এর Lot নং 7225119 Chad, Côte d'Ivoire এবং Mali এর বাজারে নকল (Falsified) হিসাবে পাওয়া গিয়েছে। উল্লেখ্য যে, ল্যাবরেটরিতে বিশ্লেষণ করে দেখা গেছে, 7225119 Lot এর ঔষধটিতে কোন Active Ingredient (Artemether/Lumefantrine) এর অস্তিত্ব নাই। ঔষধটির প্যাকেট এর গায়ে মেয়াদউত্তীর্ণের তারিখ 10/2021 কিন্তু ব্লিস্টারের গায়ে 10/2022 এবং Tanzania এর রেজিস্ট্রেশন নং TZ13H260 মুদ্রিত রয়েছে।

Table 1: Products subject of WHO Medical Product Alert N°8/2021	
Product Name	COMBIART Artemether/Lumefantrine Tablets (20/120mg)
Stated manufacturer	Strides Arcolab Ltd.
Batch / Lot	7225119
Exp date	10/2022
Identified in	Chad, Côte d'Ivoire, Mali
Packaging language	English



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


২৯/১০/২০২১

মোঃ আসরাফ হোসেন

উপপরিচালক

ঔষধ প্রশাসন অধিদপ্তর, ঢাকা।

ফোনঃ ০২২২২২-৮০৮০৩

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সংযুক্তিঃ ০২(দুই) পাতা।

Ref. RPQ/REG/ISF/Alert N°8/2021

21 December 2021

Medical Product Alert N°8/2021

Falsified Combiart identified in WHO region of Africa

Alert Summary

This WHO Medical Product Alert refers to one batch of falsified Combiart (combination of artemether and lumefantrine) identified in Chad, Côte d'Ivoire and Mali and reported to WHO in November 2021. The genuine manufacturer of Combiart, has confirmed that the product listed in this alert is falsified. The falsified product was reported at patient level outside authorized and regulated supply chains in the above-mentioned countries.

Genuine Combiart is indicated for the treatment of acute, uncomplicated malaria infections due to *Plasmodium falciparum*, and is effective in geographical regions where resistance to chloroquine has been reported.

The products identified in this alert are confirmed as falsified on the basis that they deliberately/fraudulently misrepresent their identity, composition or source. Laboratory analyses of the products found were conducted and the two expected active ingredients (artemether and lumefantrine) were not detected.

Distinguishing features of the falsification:

- The expiry date on the packaging is 10/2021, while the expiry date on the blister is 10/2022
- The falsified product has a Tanzania Reg No TZ13H260 on the blister

Table 1: Products subject of WHO Medical Product Alert N°8/2021

Product Name	COMBIART Artemether/Lumefantrine Tablets (20/120mg)
Stated manufacturer	Strides Arcolab Ltd.
Lot	7225119
Expiry date	10/2022
Packaging language	English
Identified in	Chad, Côte d'Ivoire, Mali

For photographs of the above products, please refer to Table 2.

Advice to regulatory authorities and the public

WHO requests increased attention within the supply chains of countries and regions likely to be affected by these falsified products due to prevalence of malaria caused by *Plasmodium falciparum*. Increased surveillance 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°8/2021

Falsified Combiart, Lot 7225119

identified in Chad, Côte d'Ivoire and Mali



WHO Global Surveillance and Monitoring System for Substandard and Falsified Medical Products
 For more information, please visit our [website](http://www.who.int). Email: rapidalert@who.int