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

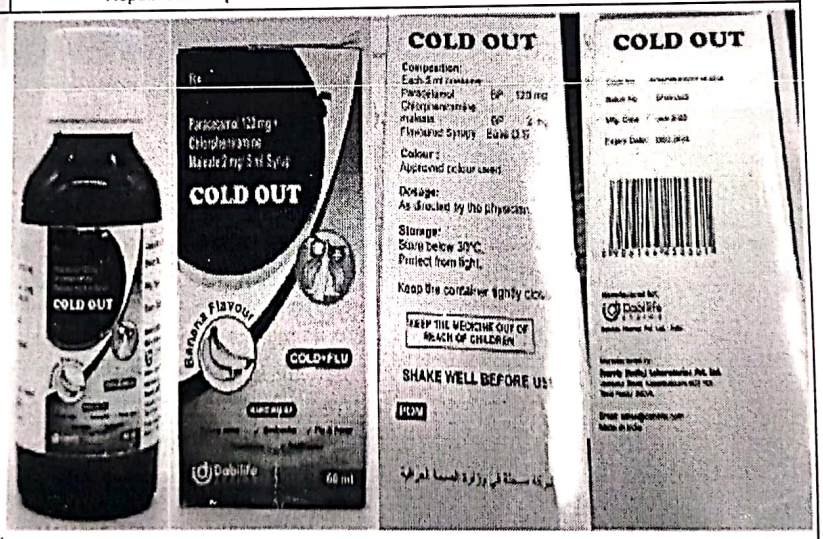
নং- ডিজিডিএ/ এলার্ট-নোটিশ/এমসি-১৬/২০১৯ ২৫৯৭৯ তারিখঃ ২৬/০৮/২০২৩ খ্রীঃ

অফিস আদেশ

ঔষধ প্রশাসন অধিদপ্তরের মাঠ পর্যায়ের সকল কর্মকর্তাদের জানানো যাচ্ছে যে, বিশ্ব স্বাস্থ্য সংস্থা (WHO) সম্প্রতি মেডিক্যাল প্রোডাক্ট এলার্ট 6/2023 এ এই মর্মে সতর্ক করেছে যে, FOURRTS (INDIA) LABORATORIES PVT. LTD কর্তৃক উৎপাদিত DABILIFE PHARMA PVT. LTD. - INDIA কর্তৃক বাজারজাতকৃত COLD OUT SYRUP এর একটি মান বহির্ভূত (ভেজাল) ব্যাচ ইরাকের বাজারে পাওয়া যাচ্ছে। কমন কোল্ড ও এল্যার্জিক লক্ষণ নিরাময়ে ব্যবহৃত উক্ত COLD OUT SYRUP টি ল্যাবরেটরীতে পরীক্ষা করা হলে দেখা যায় যে, এতে Di-Ethylene Glycol ও Ethylene Glycol অগ্রহণযোগ্য মাত্রায় কন্টামিনেন্ট বা ভেজাল হিসেবে আছে। Di-Ethylene Glycol ও Ethylene Glycol মানব শরীরের জন্য ক্ষতিকর ও অনেক ক্ষেত্রে প্রাণঘাতি।

Falsified
মেডিক্যাল প্রোডাক্টের বর্ণনাঃ

Annex: Batch of Product subject of WHO Medical Product Alert No.6/2023

Product name	COLD OUT syrup
Stated manufacturer	FOURRTS (INDIA) LABORATORIES PVT. LTD
Stated marketer	DABILIFE PHARMA PVT. LTD. - INDIA
Batch	SF001A02
Expiry date	DEC.2024
Identified in	Republic of Iraq
Available photos	

এমতাবস্থায় উল্লেখিত COLD OUT SYRUP টি বাজারে পাওয়া গেলে তা জব্দ করে প্রয়োজনীয় ব্যবস্থা গ্রহণের জন্য এতদ্বারা নির্দেশ প্রদান করা গেল।

২৬/০৮/২০২৩.

মোঃ আসরাফ হোসেন
পরিচালক
ও
হেড অব মার্কেট সার্ভিল্যান্স এন্ড কন্ট্রোল
ঔষধ প্রশাসন অধিদপ্তর, ঢাকা।
ফোনঃ ০২২২২২-৮০৮০৩
মোবাইলঃ ০১৮১৯-১৪০৪২১
Email: dgda.gov@gmail.com

১. সংযুক্তিঃ ০২ (দুই) পাতা

World Health Organization

7 August 2023

Medical Product Alert No. 6/2023
Substandard (contaminated) syrup medicines identified in WHO Region of the Eastern Mediterranean

Alert Summary

This WHO Medical Product Alert refers to one batch of substandard (contaminated) COLD OUT syrup (Paracetamol and Chlorpheniramine Maleate) identified in the Republic of Iraq and reported to the World Health Organization (WHO) on 10 July 2023 by a third party. Please refer to the Annex of this Alert for full details of the affected batch of the product.

Paracetamol and chlorpheniramine combination syrups are used to treat and relieve symptoms of the common cold and allergy symptoms.

A sample of the COLD OUT Syrup was obtained from one location in Iraq and submitted for laboratory analysis. The sample was found to contain unacceptable amounts of diethylene glycol (0.25%) and ethylene glycol (2.1%) as contaminants. The acceptable safety limit for both ethylene glycol and diethylene glycol is **no more than 0.10%.**

The stated manufacturer of the affected batch of the product is FOURRTS (INDIA) LABORATORIES PVT. LTD, and the product is stated to be manufactured for DABILIFE PHARMA PVT. LTD. - INDIA. To date, the stated manufacturer and the marketer have not provided guarantees to WHO on the safety and quality of the product.

The product referenced in this Alert may have marketing authorizations in other countries or regions. It may also have been distributed, through informal markets, to other countries.

Please refer to the Annex of this Alert for full details of the affected batch of the product.

WHO has previously published **five Alerts on other contaminated liquid dosage medicines**. Please see Medical Product Alert N°6/2022, Medical Product Alert N°7/2022, Medical Product Alert N°1/2023, Medical Product Alert N°4/2023, and Medical Product Alert N°5/2023.

Risks

Diethylene glycol and ethylene glycol are toxic to humans when consumed and can prove fatal. The substandard batch of the product referenced in this Alert is unsafe and its use, especially in children, may result in serious injury or death. Toxic effects can include abdominal pain, vomiting, diarrhoea, inability to pass urine, headache, altered mental state and acute kidney injury which may lead to death.

Advice to regulatory authorities and the public

If you have the affected product, WHO recommends that you do not use it. If you, or someone you know, has, or may have used the affected product, or suffered an adverse reaction or unexpected side-effects after use, you are advised to seek immediate medical advice from a healthcare professional.

While this Medical Product Alert relates to only one batch of the product (as set forth in the Annex hereto), out of an abundance of caution, WHO recommends increased vigilance and testing in respect of the product in general.

WHO requests increased surveillance and diligence within the supply chains of countries and regions likely to be affected by the product. Increased surveillance of the informal/unregulated market is also advised. National regulatory authorities/health authorities are advised to immediately notify WHO of any substandard/falsified products discovered in their respective country.

Manufacturers of liquid dosage forms, especially syrups that contain excipients including propylene glycol, polyethyleneglycol, sorbitol, and/or glycerin/glycerol, are urged to test for the presence of contaminants such as ethylene glycol and diethylene glycol before use in medicines.

Healthcare professionals should promptly report any suspicious or confirmed cases of adverse events linked to the use of contaminated medicines to the National Regulatory Authorities/National Pharmacovigilance Centre.

If you have any information about the manufacture or supply of any contaminated batch of this product, please contact WHO via rapidalert@who.int.

Annex: Batch of Product subject of WHO Medical Product Alert No.6/2023

Product name	COLD OUT syrup
Stated manufacturer	FOURRTS (INDIA) LABORATORIES PVT. LTD
Stated marketer	DABILIFE PHARMA PVT. LTD. - INDIA
Batch	SF001A02
Expiry date	DEC.2024
Identified in	Republic of Iraq
Available photos