RAPID ALERT

DRAP ALERT No: I/S/10-24-39

RECALL OF 04 BATCHES OF ORAL SYRUPS DUE TO CONTAMINATION OF ETHYLENE GLYCOL IMPURITIES

Date: 25th October, 2024.

Target Audience:

- National Regulatory Field Force of DRAP and Provincial Drug Control Departments.
- Healthcare Professionals (Physicians, Pharmacists & Nurses).
- General Public

Alert Summary:

The Directorate of Drugs Control (DDC) Punjab has informed DRAP that samples of the following products have been identified as contaminated with DEG/EG impurities based on analysis conducted by the Drug Testing Laboratories Punjab. Details of the affected products batches are as under:

S#	Product Name	Composition	Batch No.	Manufactured by	Test Results
01	Zonid Suspension 120ml Reg# 022579	Metronidazole 200mg/5ml	Z266	M/s. Bloom Pharmaceuticals (Pvt.) Ltd., Hattar.	Contains Ethylene Glycol Above Permissible limits
02	Hedazol Suspension 60ml Reg# 046146	Metronidazole 200mg/5ml	7037	M/s. Heal Pharmaceuticals (Pvt.) Ltd., Peshawar.	
03	Vometol Suspension 120ml Reg# 094719	Domperidone 5mg/5ml	1347	M/s. Roryan Pharmceutical Industries (Pvt.) Ltd., Peshawar.	
04	Tritadin Syrup 60ml Reg# 096413	Loratadine 1mg/ml	005	M/s. Trillium Pharmaceuticals (Pvt.) Ltd., Faisalabad.	

Risk Statement:

Ethylene Glycol (EG) contaminated oral preparations can lead to serious health risks. When ingested, EG and DEG are converted into toxic metabolites that can affect the central nervous system and heart. Moreover, it can also cause kidney damage which may lead to fatal consequences.

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Action initiated:

The manufacturers have been directed to immediately recall the defective batches of their products from the market. The field force under administrative control of DRAP and Provincial Drug Control departments have been directed to immediately conduct market surveys for detection of presence and removal of mentioned batches from the market

Advice for Pharmacies/Medical stores:

All pharmacists and chemist working at distributions and pharmacies should **immediately check** their stocks and stop supplying mentioned products. The remaining stocks should be quarantined and returned to the supplier/company. Regulatory field force of all federating units (DRAP and Provincial Health Departments) should also increase surveillance in the market to ensure the effective recall of defective products(s).

Advice for Healthcare Professionals:

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by batches of mentioned products. Adverse reactions or quality problems experienced with the use of these products are to be reported to the National Pharmacovigilance Centre (NPC), DRAP using Adverse Event Reporting Form or online through this link. Further information of reporting problems to DRAP is available on this link.

Advice for Consumers / General public:

Consumers should stop using products bearing the affected batch number(s) and shall contact to their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product, and report the incident to Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

Drug Regulatory Authority of Pakistan
محفوظ، موئثر اور معیاری اشیائے علاج

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