RAPID ALERT

DRAP ALERT No: I/S/9-24-32

RECALL OF LIQUID PREPARATIONS DUE TO ETHYLENE GLYCOL (EG) AND DIETHYLENE GLYCOL (DEG) CONTAMINATION

Date: 06th September, 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 identified contamination with ethylene glycol and diethylene glycol in the following liquid preparations. Analysis from Drug Testing Laboratories (DTLs) has declared these products as Substandard. The details of the affected batches are as follows:

S#	Product Name	Composition	Batch No.	Manufactured by
01	**Cestonil Plus syrup** Reg. No. 021843	Thiamine 1.75mg, Riboflavin 2.62mg, Pyridoxine 1.54mg, Nicotinamide 10.50mg	**061357**	M/s. Razzee Therapeutics, Lahore
02	**Texcol DM 10mg/5ml syrup** Reg. No. 025034	Dextromethorphan	**09980**	
03	**Speczine 5mg/5ml Syrup** Reg. No. 012597	Promethazine	**280** **287**	M/s. Spectrum Laboratories, Lahore
04	**Aphylin Syrup** Reg. No. 026635	Aminophylline 32mg, Diphenhydramine 8mg, Ammonium HCl 30mg	**24B056**	M/s. Obsons Pharmaceuticals, Lahore
05	**Zolint Suspension** Reg. No. 016494	Furazolidone 25mg/5ml, Metronidazole 75mg/5ml	**24003**	M/s. Libra Private Ltd., Peshawar

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Risk Statement:

Di-ethylene Glycol (DEG) and 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.

Action initiated:

All pharmacists and chemists working at distributions and pharmacies should **immediately check** their stocks and stop supplying these products. The remaining stocks should be quarantined and returned to the supplier/company. The Regulatory Field Force of all federating units (DRAP and Provincial Health Departments) has increased 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 these 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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