



RAPID ALERT

DRAP ALERT No: I/S/9-24-33

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

Date: 10th 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 of Ethylene Glycol in following liquid preparations. Drug Testing Laboratories (DTLs) has declared these batches of products as Substandard based on their analysis which revealed the presence of Ethylene Glycol exceeding limits. The details of the affected batches are as follows:

S#	Product Name	Composition	Batch No.	Manufactured by
01	Texcol EX Syrup 120ml Reg. No. 030897	Aceylline Piperazine 45mg/5ml, Diphenhydramine HCl 8mg/5ml	63864	M/s. Razee Therapeutics (Pvt.) Ltd., Lahore
02	Speczine Syrup 120ml Reg. No. 012597	Promethazine HCl 5mg/5ml	609 604 YZ	M/s. Spectrum Laboratories, Lahore
03	Mexair Syrup 60ml Reg. No. 02665	Terbutaline Sulphate 1.5mg/5ml	05-23 02-22	M/s. Siza Int., Lahore
04	Stazin Syrup 60ml Reg. no. 026326	Cetirizine HCl 5mg/5ml	GI 83	M/s. Munawar Pharma (Pvt.) Ltd., Lahore
05	Zevirol Expectorant syrup 120ml Reg. No. 009378	Dipenhydramine HCl 13.5mg, Ammonium Chloride 131.5mg, sodium citrate 55mg, Menthol 1mg	4031	P.D.H. Laboratories Lahore



DRAP, Islamabad

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06	Stazin Syrup 60ml Reg. No. 026326	Cetirizine HCl 5mg/5ml	GI83	M/s. Munawar Pharma Lahore
07	Zevirol Expectorant syrup 120ml Reg. No. 009.78	Diphenhydramine 13.5mg, Ammonium Chloride 131.5mg	4031	M/s. P.D.H. Pharmaceuticals Lahore
08	Aphylin Expectorant Syrup Reg. No. 026635	Aminophylline 32mg/5ml, Diphenhydramine 8mg/5ml, Amonium Chloride 30mg/5ml	24C090	M/s. Obsons Pharmaceuticals Lahore
09	Resfyl Syrup Reg. No. 057214	Acefylline Piperzine 45mg/5ml, Diphenhydramine 8mg/5ml	4A055	M/s. Rasco Pharma Lahore
10	Zonid Suspension 120ml Reg. No. 022579	Metronidazole 200mg/5ml	Z492 Z246	M/s. Bloom Pharmaceuticals Hattar
11	Butamin Syrup 60ml Reg. No. 016630	Salbutamol 2mg	4016	M/s. P.D.H Pharmaceuticals, Lahore
12	Nuocid Plus suspension 120ml Enlst. No. 0327660558	Zingiber Officinale 20mg/5ml, Mentha Piperita 40mg/5ml	NC- S045	M/s. Arber Pharma Lahore

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:

The manufacturers of products have been directed to **immediately recall** the defective batches of from the market. The Regulatory field force of all federating units (DRAP, Provincial Drug and States) has 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.

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

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