MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/11-23-40

RECALL OF LIQUID PREPARATIONS FOR SUSPECTED CONTAMINATION OF DIETHYLENE GLYCOL (DEG) AND ETHYLENE GLYCOL (EG)

(MANUFACTURED BY M/S. PHARMIX LABORATORIES (PVT.) LTD., LAHORE)

Date: 16th November, 2023.

Target Audience:

- Pharmacists and Chemists at Distribution, Pharmacies and Medical Stores
- Healthcare Professionals- Physicians, Pharmacists, and Nurses at hospital and clinics etc.
- General Public

Alert Summary:

DRAP has issued a recall of certain batches of liquid preparations due to suspected contamination with diethylene glycol (DEG) and ethylene glycol (EG). WHO has also informed the suspected presence of DEG/EG impurities in batch No. B220 of Alergo Syrup, (identified in the Maldives) which was manufactured by M/s. Pharmix Laboratories (Pvt.) Ltd., Lahore. Following a preliminary investigation conducted by DRAP Lahore, it is suspected that these impurities may also be present in other batches and products mentioned below. This recall is a precautionary measure taken to safeguard public health against the potential harmful effects of these impurities.

The details of suspected products and their batches are as under: -

S. No.	Product Name	Batch Nos.	Manufactured by
01.	Mucorid Syrup	A230 C227 A211 A212 B201 L111 A210 A230 B224 L121 C210 B201 B225	M/s. Pharmix Laboratories (Pvt.) Ltd., 21-Km Ferozpur Road, Lahore.
02.	Ulcofin Suspension	B209, C223	-do-
03.	Alergo syrup	B220, L126	-do-
04.	Emidone Suspension	B227	-do-
05.	Zincell Syrup	C218	-do-

Risk Statement:

Between 2022 and 2023, several countries reported incidents of oral liquid drugs that were intended for children and were found to be contaminated with high levels of DEG and EG. These incidents lead to severe adverse events and fatalities in few countries.

Action Initiated: -

The manufacturing company has been directed to immediately recall the defective batches of the above-mentioned products from the market. All pharmacists and chemists working at distributions and pharmacies are hereby advised to **immediately check** their stocks and stop supplying these batches of suspected products. The remaining stock should be quarantined and returned to the supplier/ company. The regulatory field force of DRAP and Provincial Health Departments are also informed regarding the matter and are directed to 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 this affected batch of products. Adverse reactions or quality problems experienced with the use of this product may be reported to the National Pharmacovigilance Centre (NPC), DRAP using the 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 this product 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.

All therapeutic goods must be obtained from the licensed pharmacies, and other authorized retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professional in case of any doubt.

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

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