PRODUCT RECALL ALERT

DRAP ALERT NO. Nº I/S/04-24-18

RECALL OF ETHYLENE GLYCOL CONTAMINATED SYRUPS

(MANUFACTURED BY M/S. BIOLABS (PVT.) LTD., ISLAMABAD)

Date: 29th April 2024.

Target Audience:

- National Regulatory Field Force.
- Pharmacists and Chemists at Distribution, Pharmacies and Medical Stores
- Healthcare Professionals- Physicians, Pharmacists, and Nurses at hospital and clinics etc.

Alert Summary:

The Federal Government Analyst, CDL Karachi has declared the following batches of oral liquid preparations manufactured by M/s Biolab Pvt Ltd, Islamabad as of "Sub-standard" quality based on the presence of Ethylene Glycol impurity at an unacceptable level.

Details of the affected products are as under:

Product Name	Composition	Batch Details	Manufactured by	Remarks
Mebzole 100mg/5mL Suspension Reg No. 046308	Mebendazole	**Batch No. 22J022(F)** Mfg. Date: 09-22 Exp. date: 08-24	M/s. Biolabs (Pvt.) Ltd., Islamabad.	Ethylene glycol: 1.2134% **Does not comply**
		Batch No. 22J022(B) Mfg. Date: 09-22 Exp. date: 08-24		Ethylene glycol: 1.3273% **Does not comply**
Bioris 1mg/ml Oral Solution Reg No. 069917	Risperidone	**Batch No. 23B061** Mfg. Date: 02-23 Exp. date: 01-25		Ethylene glycol: 0.8431% **Does not comply**

Risk Assessment: -

The presence of **Ethylene Glycol (EG)** in oral liquid preparations poses **serious health risks** due to its toxicity as small amounts of EG can be fatal, especially for children. When ingested, both **diethylene glycol (DEG)** and EG are metabolized into toxic compounds that can adversely affect the central nervous system, heart, and kidneys.

DRAP, Islamabad
92 51 9107404
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Action Initiated: -

The manufacturer has been directed to immediately recall the defective batches of affected products from the market. All pharmacists and chemists working at distributions and pharmacies should **immediately check** their stocks and stop supplying these batches of products. The remaining stock should be quarantined and returned to the supplier/ company. The regulatory field force of all federating units (DRAP and Provincial Health Departments) has also increased surveillance in the market to ensure the effective recall of defective products(s).

-Distributors and pharmacies are advised to be vigilant and report any suspected batch of the product(s) in the supply chain to the DRAP using the online form, or through phone at +92 51 910 73 17, or by Email at gsms@dra.gov.pk.

Advice for Healthcare Professionals: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by these affected batches 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 on 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 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 the Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

All therapeutic goods must be obtained from 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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