PRODUCT RECALL ALERT

DRAP ALERT NO. N^{o} I/S/04-24-17

RECALL OF ARTECID 75mg/3mL INJECTION (DICLOFENAC SODIUM) DUE TO THE PRESENCE OF ETHYLENE GLYCOL IMPURITIY

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

Date: 28th April, 2024.

Target Audience:

- National Regulatory Field Force.
- Pharmacists and Chemists working at Pharmacies and Medical stores
- Physicians, Pharmacists, and Nursing staff working at healthcare facilities.
- General Public

Alert Summary:

The Federal Government Analyst, CDL Karachi has declared the following products as "Adulterated" based on the presence of Ethylene Glycol impurity, manufactured by M/s. Biolabs (Private) Limited, Islamabad:

Product Name	Batch Details	Manufactured by	Remarks
Artecid Injection Contains: Diclofenac Sodium 75mg/3ml	**Batch No. 23E018** Mfg. Date: 05-23 Exp. date: 04-25	M/s. Biolabs (Private) Limited, Islamabad.	The sample is "**Adulterated**" due to the presence of the following impurities: **Ethylene Glycol: 19.66%**

Risk Assessment: -

EG (Ethylene Glycol) is a toxic substance that can have serious adverse effects. EG is metabolized into toxic metabolites that can affect the central nervous system, and heart, and can cause kidney damage, which can be fatal. Although, there is no available data on the systemic absorption of injected EG, and no instances of human or animal toxicity from injection of EG have been reported in the literature.

Action Initiated: -

The manufacturer has been directed to immediately recall the defective batch of product from the market. All pharmacists and chemists working at distributions and pharmacies should **immediately check** their stocks and stop supplying this batch of product. 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) should also increase 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 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 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 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 the 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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