VETERINARY PRODUCT RECALL ALERT

DRAP ALERT NO. N^{o} I/S/04-24-16

RECALL OF INJECTIONS FOR VETERINARY USE DUE TO THE PRESENCE OF ETHYLENE GLYCOL AND DIETHYLENE GLYCOL IMPURITIES

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

Date: 28th April, 2024.

Target Audience:

- National Regulatory Field Force.
- Points of sale and distributors of veterinary medicine.
- Veterinary Doctors and professionals.
- General Public

Alert Summary:

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

Product Name	Batch Details	Manufactured by	Remarks
Clo-Animectin Injection Contains: Clorsulon 100mg/ml Ivermectin 10mg/ml	**Batch No. 009A24** Mfg. Date: 01-24 Exp. date: 12-25	M/s. Biolabs (Private) limited, Islamabad.	Sample is "**Adulterated**" due to presence of following impurities: **Ethylene Glycol: 14.36%** **Diethylene Glycol: 2.92%**
Bio-Oxicam 0.75% Injection Contains: Meloxicam 7.5mg/ml	**Batch No. 083C23** Mfg. Date: 03-23 Exp. date: 02-25	M/s. Biolabs (Private) limited, Islamabad.	Sample is "**Adulterated**" due to presence of following impurities: **Ethylene Glycol: 24.19%**
Bio-E-Floxacin 10% Injection Contains: Enrofloxacin 100mg/ml	**Batch No. 047K22** Mfg. Date: 10-22 Exp. date: 09-24	M/s. Biolabs (Private) limited, Islamabad.	Sample is "**Adulterated**" due to presence of following impurities: **Ethylene Glycol: 12.08%**

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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 defected batch of product from the market. All personnel working at distributions and point of sales of veterinary medicine should **immediately check** their stocks and stop supplying this batch of product. The remaining stock should be quarantined and returned to the supplier/ company. 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 point of sales (pharmacies and medical stores) 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 Veterinary Professionals: -

DRAP requests increased vigilance within the supply chains of veterinary pharmacies and veterinary healthcare facilities likely to be affected by this affected batch of product.

Drug Regulatory Authority of Pakistan
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