MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/2-25-24

RECALL OF SUBSTANDARD FLOONIX INJECTION (BATCH # INJ-175) MANUFACTURED BY M/S KAYANS PHARMACEUTICALS, ISLAMABAD.

Date: 25th February, 2025

Target Audience:

- National Regulatory Field Force of DRAP and Provincial Drug Control Departments.
- Healthcare Professionals (Physicians, Pharmacists & Nurses).
- General Public.

Alert Summary:

Federal Government Analyst, Central Drugs Laboratory Karachi vide test/analysis No. IP-12-24-000101 dated 13-02-2025, has declared the sample of Floonix Injection (Batch # INJ-175), manufactured by M/s Kayans Pharmaceuticals, Islamabad, as '***Substandard'***. Details of test/analysis report are given as under:

S#	Product Name	Batch Details	Manufacturer	Remarks
1.	**Floonix Injection** (Flunixin 50mg/ml) For Veterinary use only. Reg. No. 112247	No: INJ-175 Mfg date: 11-2024 Expiry date: 11-2026	M/s. Kayans Pharmaceuticals. Islamabad.	***'Substandard'*** on the basis of Assay. Flunixin: 70.79%; Acceptance criteria: 90% - 110%.

Risk Statement:

The use of substandard products can result in therapy failure, increasing the risk of complications, particularly in vulnerable groups such as immunocompromised individuals, as well as pediatric and geriatric population.

Action initiated: -

The field force under administrative control of DRAP and Provincial Drug Control departments have been directed to immediately conduct market surveys for detection of presence and removal of defective batch of mentioned drug 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 the mentioned product. The remaining stocks 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).

Advice for Veterinarians: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by the mentioned batch of the product. Further information on reporting problems to DRAP is available on this link.

Advice for Farmers / Consumers: -

Farmers / Consumers should stop using product bearing the affected batch number(s) and shall contact to their veterinarian or healthcare provider if the animal experienced any problem that may be related to using this drug product.

Drug Regulatory Authority of Pakistan
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