RAPID ALERT

DRAP ALERT No: I/S/11-24-45

RECALL OF 04 BATCHES OF DRUG PRODUCTS FROM MARKET

Date: 08th November, 2024.

Target Audience:

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

Alert Summary:

Directorate of Drugs Control (DDC) Punjab has informed DRAP that samples following products have been analyzed by the provincial DTLs in Punjab and have been declared as substandard due to reasons mentioned below. The detail of affected products is as under:

S#	Product Name	Composition	Batch No.	Manufactured by	Test Results
01	Nida Infusion 100ml Reg. No. 079630	Metronidazole 500mg/100ml	23E317	GMP Pharmaceuticals, 28-Km Sheikhupura Road, Lahore.	Substandard due to visible particles and Bacterial Endotoxin.
02	Metroin Infusion 100ml Reg. No. 071279	Metronidazole 500mg/100ml	MT24-055	Saturn Pharmaceuticals, 23-Km, thokar Raiwind Road, Lahore	Substandard due to presence of visible particles.
03	Tylosan 20 Injection 100ml Reg. No. 027416 (For vet use only)	Tylosin base 200mg/ml	TS-259	Sanna Laboratories, 1019-B, P.I.S.E., Sargodha road, Faisalabad.	Substandard due to presence of visible particles.
04	Melacam-10 injection 50ml Reg. No. 063542 (For vet use only)	Meloxicam 10mg/ml	23U-03	Medi-vet (Pvt) Ltd., 17-Km Sheikhupura road, Lahore	Substandard on the basis of visible particles and extractable volume.

Risk Statement:

Administration of products containing visible solid particles and/or bacterial endotoxins through IV infusion may lead to complications, such venous thromboembolism, septic shock etc. which may have fatal consequences.

DRAP, Islamabad | + 92 051 9255969 | gsms@dra.gov.pk

Action Initiated:

The manufacturing companies of these products have been directed to immediately recall the affected batches of their products from the market. The Regulatory Field Force of DRAP and Provincial Drug Control Administrations have been directed to conduct market surveys for monitoring the recall process to ensure effective removal of defective batches 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 mentioned products. 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 have increased 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 batches of mentioned products. Adverse reactions or quality problems experienced with the use of these products are to be reported to the National Pharmacovigilance Centre (NPC), DRAP using Adverse Event Reporting Form or online through this link. Further information of reporting problems to DRAP is available on this link.

Advice for Veterinary Professionals:

DRAP requests increased vigilance within the supply chains of veterinary pharmacies and facilities likely to be affected by this faulty batch. Quality problems experienced with the use of this product may be reported to DRAP through this link.

Advice for Consumers / General Public:

Consumers should stop using products 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.

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

DRAP, Islamabad
+ 92 051 9255969
gsms@dra.gov.pk