MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/11-24-51

RECALL OF 06 BATCHES OF NEUTROZOLE INFUSION

(Manufactured by M/s Neutro Pharma (Pvt.) Ltd, Lahore)

Date: 29th November, 2024

Target Audience:

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

Alert Summary:

The Provincial Inspector of Drugs, Punjab collected the samples of Neutrozole Infusion from various districts of Punjab and sent for test / analysis. The Drugs Testing Laboratory, Multan has declared various batches the said product, manufactured by M/s Neutro Pharma (Pvt.) Ltd, Lahore, as a Substandard product. The details of the case are as under:

S#	Product Name	Composition	Batch details	Manufactured by
01	Neutrozole Infusion 100ml Reg. No. 046878	Metronidazole (500mg/100ml)	Batch No. MZ023, MZ028, MZ010, MZ007, MZ006, MZ003	M/s. Neutro Pharma (Pvt.) Ltd., 9.5 Km, Sheikhupura Road, Lahore-Pakistan.

Risk Statement:

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

Action initiated: -

The manufacturer has been directed to immediately recall the defective batch of product from the market. 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 mentioned batch 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 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 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 above mentioned product 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 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
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