MEDICAL PRODUCT ALERT

DRAP ALERT NO. N^{o} I/S/09-24-30

RECALL OF SUBSTANDARD BATCHES OF PHARMACEUTICAL PRODUCTS

Date: 06th September, 2024.

Target Audience:

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

Alert Summary:

The Directorate of Drugs Control (DDC) in Punjab and the Quality Control Board in Baluchistan have identified the following substandard batches of pharmaceutical products based on analyzing their samples from Drug Testing Laboratories, revealing out-of-specification results. The details of substandard batches are as under:

S#	Product Name	Active Ingredients	Batch No.	Manufactured by	Test Results
01	Zyocain gel 15g	Lidocaine HCL 2%	244 275	M/s. Pharmawise Laboratories, Lahore	Substandard
02	Metrorise injection	Metronidazole 500mg/100ml	LV 2303	M/s. Pak risen Pharmaceuticals, Hattar	Substandard
03	Safemed Injection	Metronidazole 500mg/100ml	S-825	M/s. Ahad International Pharmaceutical Ltd., DI Khan	Substandard
04	Lyosafe Infusion	Levofloxacin	L-784		Substandard
05	Enzol-WFI injection	Sterile water for injection	1240003	M/s. Enzon Pharma, Lahore	Substandard
06	Oxytofas Injection	Oxytocin	OTI-1419	M/s. Intervac (Pvt.) Ltd., Sheikhupura	Substandard &Misbranded
07	Painsa 75mg Injection	Diclofenac Sodium	PA420	M/s. Wimits Pharmaceuticals, Lahore	Substandard
08	Midoven Injection	Furosemide	H-21924	M/s. Venus Pharma, Lahore	Adulterated
09	Mencobal Injection	Mecobalamin	083 084	M/s. Treat Pharmaceutical Industry, Lahore	Adulterated

Risk Statement:

The impact of use of Substandard/Adulterated products may lead to sub-optimal therapeutic effects which may lead to therapy failure or other associated problems.

Action initiated: -

The manufacturing companies have been directed to **immediately recall their products** of defective batches from the market. All **pharmacists and chemists** working at distributions and pharmacies should **immediately check** their stocks and stop supplying defective products. Any remaining stocks should be quarantined and returned to the supplier/company. The Regulatory field force of all federating units (DRAP and Provincial Health Departments) has increased market surveillance to ensure the effective removal 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 defective batches of these 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 the 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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