MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/09-24-49

Recall Of Substandard Flagynase Suspension (Reg. No. 087528) Batch No. 0362 Manufactured By M/S Aries Pharmaceuticals (Pvt.) Ltd, Peshawar.

Date: 20th 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 Federal Inspector of Drugs, Peshawar collected the samples of Flagynase Suspension and sent for test / analysis. The Central Drugs Laboratory, Karachi has declared batch No. 0362 of the said product, manufactured by M/s Aries Pharmaceuticals (Pvt.) Ltd, Peshawar, as a Substandard product.

S#	Product Name	Composition	Batch details	Manufactured by
01	Flagynase suspension Reg. No. 087528	Metronidazole (200mg/5ml)	Batch no. 0362 Mfg date: 10/23 Expiry date: 10/25	M/s. Aries Pharmaceuticals (Pvt.) Ltd., 1-W, Industrial Estate, Hayatabad, Peshawar.

Risk Statement:

Metronidazole Oral Suspension is indicated in the prophylaxis and treatment of infections in which anaerobic bacteria have been identified or suspected. Use of substandard products may lead to suboptimal to no-therapeutic effects and may contribute to drug resistance, and can also intensify/exacerbate the existing bacterial infection.

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 mentioned batch from the market.

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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
محفوظ، موثر اور معیاری اشیائے علاج

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