MEDICAL PRODUCT ALERT

DRAP ALERT NO. Nº I/S/01-25-03

RECALL OF SUBSTANDARD CEFRADIN CAPSULES BATCH NO. 3591 MANUFACTURED BY M/S ARIES PHARMACEUTICALS (PVT.) LTD, PESHAWAR.

Date: 02th January, 2025

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 Cefradin Capsules and sent for test / analysis. The Central Drugs Laboratory, Karachi has declared batch No. 3591 of the said product, manufactured by M/s Aries Pharmaceuticals (Pvt.) Ltd, Peshawar, as of Substandard quality.

S#	Product Name	Composition	Batch details	Manufactured by
01	Cefradin Capsule Reg. No. 036991	Cefradine (250mg/Capsule)	Batch no. 3591 Mfg date: 05/24 Expiry date: 05/26	M/s. Aries Pharmaceuticals (Pvt.) Ltd., 1-W, Industrial Estate, Hayatabad, Peshawar.

Risk Statement:

The cefradine capsules have been identified as substandard due to deviations in weight variation, which could impact their efficacy, safety, and quality. If the weight of the capsules is not within the prescribed limits, there is a risk of inaccurate dosing. As a result, patients may not receive the correct amount of medication, which could lead to therapeutic failure, side effects, or the development of resistance.

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.

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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