RECALL ALERT

DRAP ALERT NO. Nº I/S/10-24-41

RECALL OF SUBSTANDARD FAMILA INJECTION (BATCH NO. 083)
MANUFACTURED BY M/S ZAFA PHARMACEUTICAL LABORATORIES (PVT.) LTD, KARACHI

Date: 24th October, 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, Karachi collected the samples of Famila Injection and sent for test / analysis. The Central Drugs Laboratory, Karachi has declared batch No. 083 of Famila Injection, manufactured by M/s Zafa Pharmaceutical Laboratories (Pvt.) Ltd, Karachi, as a substandard product.

Product Name	Composition	Batch details	Manufactured by
Famila Injection 150mg Reg. No. 015615	Medroxyprogesterone acetate	Batch no. 083 Mfg date: 02/24 Expiry Date: 02/29	M/s. Zafa Pharmaceutical Laboratories (Pvt.) Ltd. L-4/1, A&B, Block-21, Federal "B" Industrial Area, Karachi-75950

Risk Statement:

To comply with the Sterility testing for injections is crucial to ensure that the product is free from viable microorganisms. The samples of above-mentioned product have been reported **substandard based on sterility failure**. The use of such product may lead to transmission of blood borne infections and serious adverse events.

Action initiated: -

The manufacturer has been directed to immediately recall the defective batch of product from the market. All pharmacists and chemists working at distributions and pharmacies should immediately check their stocks and stop supplying this batch of products. The remaining stock should be quarantined and returned to the supplier/ company.

The regulatory field force of all federating units (DRAP and Provincial Health Departments) also increased surveillance in the market to ensure the effective recall of defective products(s).

Advice for Pharmacies/Medical stores: -

All pharmacists and chemists working at distributions and pharmacies should **immediately check** their stocks and stop supplying this product. The 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 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 this product. Adverse reactions or quality problems experienced with the use of drug product shall be reported to the National Pharmacovigilance Centre (NPC), DRAP using Adverse Event Reporting Form or online through this link.

Further information on 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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