PRODUCT RECALL ALERT

DRAP ALERT NO. Nº I/S/6-24-26

RECALL OF STERILE WATER FOR INJECTION (BATCH NO. 989)

(MANUFACTURED BY ZAFA PHARMACEUTICAL LABORATORIES PVT LTD, KARACHI)

Date: 09th June 2024.

Target Audience:

- National Regulatory Field Force.
- Pharmacists and Chemists at Distribution, Pharmacies and Medical Stores
- Healthcare Professionals- Physicians, Pharmacists, and Nurses at hospital and clinics etc.

Alert Summary:

Federal Drug Inspector in Karachi collected a sample of Sterile Water for Injection and sent for laboratory analysis. Federal Government Analyst at CDL Karachi has declared Batch No. 989 of the product as substandard. Details of the affected product is as under:

Sr	Product Name	Composition	Batch Details	Manufactured by	Remarks
1	Sterile Water for Injection Reg No. 030217	Water for Injection	**Batch 989** Mfg Date:03-2023 Exp Date:03-2028	M/s. Zafa Pharmaceutical Laboratories (Pvt) Limited, Karachi	Sterility test result does not comply

Risk Assessment: -

Using non-sterile water for reconstitution of injectable medications can lead to bacterial and fungal infections, and may cause poor dissolution of the powder. It could also result in precipitation or deactivation of the active pharmaceutical ingredient, posing significant health risks.

Action Initiated: -

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

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DRAP, Islamabad 92 51 9107404 gsms@dra.gov.pk

-Distributors and pharmacies are advised to be vigilant and report any suspected batch of the product(s) in the supply chain to the DRAP using the **online form**, or through phone at +92 51 910 73 17, or by Email at gsms@dra.gov.pk.

Advice for Healthcare Professionals: -

DRAP requests increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by this affected batch of products.

Adverse reactions or quality problems experienced with the use of this product may be reported to the National Pharmacovigilance Centre (NPC), DRAP using the 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 this product 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 the Drug Regulatory Authority of Pakistan/ National Pharmacovigilance Centre.

All therapeutic goods must be obtained from the licensed pharmacies, and other authorized retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professional in case of any doubt.

Drug Regulatory Authority of Pakistan
محفوظ، موثر اور معیاری اشیائے علاج

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