PRODUCT RECALL ALERT

DRAP ALERT NO. Nº I/S/11-23-43

RECALL ALERT OF STERILE WATER FOR INJECTION (Batch #B6-77)

(MANUFACTURED BY ISIS PHARMACEAUTICALS & CHEMICAL WORKS, KARACHI)

Date: 8th December, 2023

Target Audience:

- Pharmacists and Chemists at Distribution, Pharmacies and Medical Stores
- Healthcare Professionals- Physicians, Pharmacists, and Nurses at hospital and clinics etc.
- General Public

Alert Summary:

Federal Government Analyst, CDL Karachi has informed DRAP regarding the sample of product namely "Sterile Water for Injection" Batch No. B6-77 manufactured by M/s. ISIS Pharmaceuticals & Chemical works, 25/1-4, Sector 12-C, North Karachi Industrial Area, Karachi, has been declared as of "Substandard" quality.

The detail of the affected product is as under:

Product Name	Composition	Batch	Manufactured by:	Remarks of CDL
Sterile Water for Injection Reg.No 048819	Sterile Water for Injection	Batch No. **B6-77** Mfg. Date: 08-23 Exp. date: 08-26	Ms. ISIS Pharmaceutical & Chemical Works, Karachi	The sample is of Sub-standard quality non-compliance Bacterial endotoxin limit

Risk Statement:

Sterile water for injection is a sterile, non-pyrogenic, and isotonic solution of water that does not contain any additives. It is mainly used as a solvent or diluent for other parenteral drugs, such as antibiotics and administered intravenously, intramuscularly, or subcutaneously.

Endotoxin is a toxic substance that can cause serious harm such as fever, inflammation, shock, coagulation, and immune suppression. Using endotoxin-contaminated water for injection can lead to life-threatening complications, especially if injected intravenously.

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

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 batches of product. 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) has also increased surveillance in the market to ensure the effective recall of defective products(s).

-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 product.

Adverse reactions or quality problems experienced with the use of this product should 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 this product 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, through MedSafety Mobile Application, or online at Med Vigilance E Reporting System.

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
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