



PRODUCT RECALL ALERT

DRAP ALERT NO. N° I/S/12-23-48

RECALL OF IS-NS 0.9% INFUSION (Batch #B6-24)

(MANUFACTURED BY M/s. ISIS PHARMACEUTICALS & CHEMICAL WORKS, KARACHI)

Date: 2nd January, 2024

Target Audience:

- Healthcare Professionals particularly working in the critical care areas of hospitals including Physicians, Pharmacists, and Nurses.
- Procurement Officers at Hospitals and Healthcare Institutions.
- Pharmacists and Chemists at Distribution, Pharmacies and Medical Stores.

Alert Summary:

Federal Government Analyst, CDL Karachi has declared Batch No. B6-24 of product “IS-NS 0.9% INFUSION” as of Substandard quality.

Details of the affected product is as under:

| Product Name | Composition | Batch Details | Manufactured by | Remarks |
|--------------------------------------|----------------------|--|--|---|
| IS-NS 0.9% Infusion Reg.No 104066 | 0.9% Sodium Chloride | Batch No. B6-24 Mfg. Date: 08-23 Exp. date: 08-25 | M/s ISIS Pharmaceuticals & Chemical Works, Karachi | The Sample is of Substandard Quality on the basis of assay test. |

Risk Assessment: -

The use of substandard products based on assay tests may alter the dose and hamper the efficacy of the product leading to sub-therapeutic effects.

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 DRAP and Provincial Health Departments has 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 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 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 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.

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Drug Regulatory Authority of Pakistan

محفوظ، موثر اور معیاری اشیائے علاج

