DRUG REGULATORY AUTHORITY OF PAKISTAN
Division of Quality Assurance and Laboratory Testing

RAPID ALERT

DRAP ALERT No: Nº I/S/09-25-61

Precautionary Recall of Inj. Cara-Fer (Iron Sucrose 100mg/5ml), Batch No. 24C001

Date: 12th September , 2025

Target Audience:

- Regulatory Field Force of DRAP and Provincial Drug Control departments.
- Healthcare Professionals
- Consumers

Problem Statement:

The Drug Regulatory Authority of Pakistan (DRAP) has received reports through the Directorate of Drugs Control, Punjab, regarding multiple **serious adverse drug reactions (ADRs)** in patients administered **Inj. Cara-Fer (Iron Sucrose 100mg/5ml), Batch No. 24C001**, manufactured by **M/s Caraway Pharmaceuticals,** Plot No. 12 Street No. N-3 National Industrial Zone (RCCI) Rawat.

Reported cases include **hypersensitivity reactions such as rash, angioedema, shortness of breath, hypotension, and palpitations**, which indicate potential risk of **life-threatening anaphylactic events**.

Risk Statement:

Use of **Inj. Cara-Fer (Iron Sucrose 100mg/5ml), Batch No. 24C001** may result in **serious and potentially life-threatening hypersensitivity reactions**, including anaphylaxis, especially in patients receiving intravenous iron therapy. This batch is therefore classified as a **Class I (High-Risk) Recall**.

Action initiated:

All Pharmacists, chemists, and other healthcare professionals working at distributions, pharmacies, healthcare facilities, and other aspects of the supply chain system should immediately check the stock, and information related to the suppliers of such products should be provided to the Regulatory field force (DRAP, Provincial Drug Control Departments) to ensure the removal of these product from the circulation.

DRAP, Islamabad | + 92 051 9255969 | gsms@dra.gov.pk

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Advice for Healthcare Professionals: -

- Immediately **stop use and dispensing** of **Inj. Cara-Fer (Iron Sucrose 100mg/5ml), Batch No. 24C001**.
- **Identify and monitor** patients who may have received this batch for signs of hypersensitivity or anaphylaxis.
- **Retain and segregate** any remaining stock and ensure it is not used until further instructions.
- Counsel patients regarding the risks and advise on suitable **therapeutic alternatives** where necessary.

DRAP requests healthcare professionals to have increased vigilance within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by above mentioned product. Any adverse events or quality problems experienced with the use of these products should be reported to National or Provincial pharmacovigilance centers 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:

Consumers should not use these products and should contact their physician or healthcare provider(s) if they have experienced any problem related to taking or using the above mentioned products and should report the incident to the Drug Regulatory Authority of Pakistan / National Pharmacovigilance Centre. All therapeutic goods must be obtained from licensed pharmacies and other authorized/licensed retail outlets. The authenticity and condition of products should be carefully checked. Seek advice from your pharmacists or other healthcare professionals in case of any doubt.

Drug Regulatory Authority of Pakistan

محفوظ، موثر اور معیاری اشیائے علاج

DRAP, Islamabad | + 92 051 9255969 | gsms@dra.gov.pk