



# DRUG REGULATORY AUTHORITY OF PAKISTAN

## Division of Quality Assurance and Laboratory Testing

### RAPID ALERT

DRAP ALERT No: N° I/S/03-26-11

#### SPURIOUS & SUBSTANDARD INJECTION VENOFRER 5 mL (Batch No. 4721026AA)

**Date:** 11<sup>th</sup> March, 2026

**Target Audience:**

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

**Problem Statement:**

Drug Testing Laboratory (DTL), Punjab has declared the following sample of product as **Spurious** under Section 3(zb)(ii), **Misbranded** under Section 3(s)(vi), and **Substandard** under the Drugs Act, 1976.

| S# | Product Name  | Batch No. | Manufacturer (as per label)  | Test Result   |
|----|---|-----------|--|---|
| 1  | <b>Injection Venofer 5 mL</b><br>(Iron Sucrose 100 mg/5 mL) | 4721026AA | <i>Purported to be manufactured by</i><br>Takeda Austria GmbH, Austria<br>Imported by: M/s Searle Pakistan Limited | Declared Spurious, Misbranded & Substandard (Assay failure of Iron & Sucrose) |

The product is **purported** to be manufactured by **Takeda Austria GmbH, Austria** and imported by **M/s Searle Pakistan Limited**. However, the authorized importer has officially disowned the recovered sample and confirmed, after physical comparison with their retention sample of the same batch, that the provided sample is counterfeit.

Laboratory analysis revealed failure of assay for Iron and Sucrose contents, while sterility test complied. The product also does not contain finished drug product specifications.

**Risk Statement:**

Venoferr (Iron Sucrose) is an injectable preparation indicated for the treatment of iron deficiency anemia, particularly in patients with chronic kidney disease and those undergoing dialysis. Laboratory findings demonstrated significant deviation in Iron content (113.1% of label claim; limit 95–105%) and markedly reduced Sucrose content (169 mg/mL; limit 260–340 mg/mL), confirming compromised formulation quality. The authorized importer has further confirmed that the recovered sample is counterfeit. Administration of this falsified injectable product may result in inadequate therapeutic response, unpredictable adverse reactions, and serious health risks in vulnerable patients. The public health risk is assessed as **high**.

**Action Initiated: -**

The Regulatory Field Force of DRAP and Provincial Drug Control Departments has been directed to conduct surveillance activities throughout the supply chain to confiscate the falsified products.





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### Advice for Healthcare Professionals: -

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

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