RAPID ALERT

DRAP ALERT NO. Nº I/S/06-23-25

FALSIFIED DEFITELIO 80 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION-UK/IRELAND PACK & 200MG/2.5ML INJECTION- US PACK)

Date: 19th June 2023

Target Audience:

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

Problem Statement:

WHO issued Medical Product Alert No. 3/2023 on falsified batch No. 19G19A, Expiry Date 01/2025, of DEFITELIO identified in the United Arab Emirates and publically reported by the national regulatory authority (in November 2022). The falsified batch was also identified in Kyrgyzstan (in March 2023). They have been identified in UK/Ireland packaging and US packaging. This falsified product is not registered in Pakistan.

The genuine manufacturer of DEFITELIO has confirmed that the products referenced in WHO alert are falsified. Lab analysis of a sample of falsified products found it did not contain any of the stated active ingredients. The genuine manufacturer has also advised that:

i. Stated batch number 19G19A is not a genuine DEFITELIO batch number
ii. Expiry dates are falsified
iii. Falsified US pack with batch 19G19A / Exp. 01/2025- the vial inside the pack has a different batch number- M06B466E which is not a genuine batch number.

Detail of Product*	**Batch No.**	**Purported Manufacturer**	**Remarks**
DEFITELIO 80 mg/ml Concentrate for Infusion (Defibrotide Sodium) **Registration No.: Nil**	Outer carton Batch: **19G19A** Exp. date: **01/2025** Inner vial Batch: **M06B466E**	M/s Gentium SRl	WHO has declared it Falsified Product and generated WHO alert No. 03/23.

*DRAP has never authorized the sale of above product in Pakistan. This product is neither registered nor available on the Pakistan market, however, these may have been carried for personal use while visiting other countries.

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Risk Statement:

DEFITELIO (Defibrotide sodium) is an antithrombotic agent used to treat severe venous-occlusive disease (VOD) in adult and pediatric patients undergoing hematopoietic (blood) stem cell transplantation.

- Use of falsified products will compromise the treatment of disease and may intensify the existing condition.
- It may lead to life-threatening reactions due to intravenous administration as safety, sterility and quality of product are unknown.

Action Initiated: -

The Regulatory Field Force has been directed to increase the surveillance activities at Health facilities (Hospitals) in addition to markets and confiscate the batch of products if available. All Pharmacists and chemists working at distributions and Pharmacies should **immediately check** the stock and stop supplying this batch product. The remaining stock should be quarantined immediately, and supplier(s) information should be provided to the Regulatory field force (DRAP, Provincial Health Departments, and States) in order to ensure the removal of these products.

Advice for Healthcare Professionals: -

DRAP requests increased vigilance at hospitals and within the supply chains of institutions/pharmacies/healthcare facilities likely to be affected by this product.

Adverse reactions or quality problems experienced with the use of this product shall be reported to the National Pharmacovigilance Centre(NPC), DRAP 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 / General public: -

Consumers should not use this product and shall contact their physician or healthcare provider if they have experienced any problem related to taking or using this drug product, 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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