



RAPID ALERT

DRAP ALERT NO. N° I/S/9-23-33

FALSIFIED DEFITELIO 80MG/ML INJECTION

Date: 08th September, 2023

Target Audience:

- Regulatory Field Force.
- Healthcare Professionals - Physicians, Pharmacists, and Nurses.
- General Public.

Problem Statement:

WHO has informed regarding the presence of a falsified batch of DEFITELIO (defibrotide sodium) Lot No. 20G20A detected in India (April 2023) and Türkiye (July 2023) and was supplied outside of regulated and authorized channels. This product is not registered in Pakistan however, due to its detection in the neighboring countries, it is highly likely that this product can infiltrate the Pakistani market.

DEFITELIO (defibrotide) is indicated for the treatment of severe hepatic veno-occlusive disease (VOD) also known as sinusoidal obstructive syndrome (SOS) in hematopoietic stem-cell transplantation (HSCT) therapy. It is indicated for adults, adolescents, children and infants over 1 month of age. VOD is a condition in which the veins in the liver become blocked and stops the liver from working correctly.

The genuine manufacturer of DEFITELIO has confirmed that the product referenced in this Alert is falsified. The genuine manufacturer has advised that:

- Genuine DEFITELIO with Lot 20G20A was packaged in German/Austrian packaging.
- The falsified products instead are in UK/Ireland packaging.
- The stated expiry date is falsified and does not comply with the registered shelf life.
- The stated serial number is not associated with batch 20G20A.
- DEFITELIO does not have marketing authorization in India and Türkiye.





Identification and details of falsified product:

Product Name	DEFITELIO 80 mg/mL concentrate for solution for infusion
Stated manufacturer	Gentium Srl
Packaging	UK/ Ireland packaging
Lot	20G20A
Expiry date	08 / 2024

Available Photos*:



DRAP, Islamabad



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Threats to Public Health: -

The use of falsified DEFITELIO will result in the ineffective treatment of patients and may pose other serious risks to health because of its intravenous administration and could be life-threatening in some circumstances. Moreover, the safety, sterility, and quality of the falsified products referenced in this alert are also unknown.

Action Initiated: -

The Regulatory Field Force has been directed to increase surveillance throughout the supply chain system including healthcare facilities to confiscate/seize this product from the market without any delay. Since this product is not registered with DRAP, it is not permitted to be stocked or sold in pharmacies or other retail outlets. However, it is crucial for all healthcare professionals, including pharmacists and chemists, to check their stock immediately and stop the distribution or supply of this product if it is found. Information related to the supplier of this product should be provided to the Regulatory field force (DRAP, Provincial Health Departments, and States) to ensure the removal of this product.

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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