World Health Organization

4 September 2023

Medical Product Alert No. 7/2023

Falsified DEFITELIO (defibrotide) identified in the WHO Regions of Europe and South-East Asia

Alert Summary

This WHO Medical Product Alert refers to one falsified batch of DEFITELIO (defibrotide sodium). This falsified product has been detected in India (April 2023) and Türkiye (July 2023) and was supplied outside of regulated and authorized channels.

DEFITELIO (defibrotide) is indicated for the treatment of severe hepatic veno-occlusive disease (VOD) also known as sinusoidal obstructive syndrome (SOS) in haematopoietic 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 stop the liver 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.

WHO has previously issued Alerts for falsified DEFITELIO detected in other Countries and Regions. Please refer to Medical Product Alert N°5/2020, and Medical Product Alert N°3/2023.

Please refer to the Annex of this Alert for full details of the affected products.

Risks

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.

WHO is not currently aware of any reports of adverse events following the use of this reported falsified DEFITELIO, however, the safety, sterility, and quality of the falsified products referenced in this alert are unknown.

Advice to regulatory authorities and the public

If you have any of the affected products, WHO recommends that you do not use them. If you, or someone you know, has or may have used the affected product, or suffered an adverse reaction or unexpected side-effect after use, you are advised to seek immediate medical advice from a healthcare professional.

Healthcare professionals should report the incident to the National Regulatory Authorities/National Pharmacovigilance Centre. National regulatory/health authorities are advised to immediately notify WHO if they identify these falsified products.

All medical products must be obtained from authorized/licensed suppliers. If you have any information about the manufacture or supply of these products, please contact WHO via rapidalert@who.int.

Annex: Products subject of WHO Medical Product Alert No. 7/2023

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
Identified in	India and Türkiye
Available photos*	 **Photos of product detected in Türkiye*