11 April 2023

Medical Product Alert No. 3/2023

Falsified DEFITELIO (defibrotide sodium) identified in the WHO Regions of Europe and the Eastern Mediterranean

Alert Summary

This WHO Medical Product Alert refers to a falsified batch of DEFITELIO (defibrotide sodium) identified in the United Arab Emirates and publicly reported by the national regulatory authority (in November 2022). The falsified batch was also identified in Kyrgyzstan (in March 2023).

The falsified products have been identified in UK/Ireland packaging and US packaging.

Defibrotide is an antithrombotic agent used to treat severe veno-occlusive disease (VOD) in adult and paediatric patients undergoing haematopoietic (blood) stem cell transplantation. VOD is a condition in which the veins in the liver become blocked and stop the liver working properly.

The genuine manufacturer of DEFITELIO has confirmed that the products referenced in this Alert are falsified. Laboratory analysis of a sample of the falsified product found it did not contain any of the stated active ingredient. The genuine manufacturer has also advised that:

- The stated batch number 19G19A is not a genuine DEFITELIO batch number.
- The expiry dates are falsified.
- The 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.

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 the 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.

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. 3/2023

Product Name	DEFITELIO 80 mg/mL concentrate for solution for infusion
Stated manufacturer	Gentium Srl
Batch (packaging)	19G19A
Expiry date	06/2023
Pack language	English
Packaging	UK/Ireland pack
Identified in	Kyrgyzstan and United Arab Emirates
Available photos	

Product Name	DEFITELIO (defibrotide sodium) injection 200 mg/2.5mL (80 mg/mL)
Stated manufacturer	Not reported
Batch (packaging)	19G19A
Batch (vial)	M068466E
Expiry date	01/2025
Pack language	English
Packaging	US pack
Identified in	Kyrgyzstan
Available photos