গণপ্রজাতন্ত্রী বাংলাদেশ সরকার
ঔষধ প্রশাসন অধিদপ্তর
ঔষধ ভবন, মহাখালী, ঢাকা
www.dgda.gov.bd

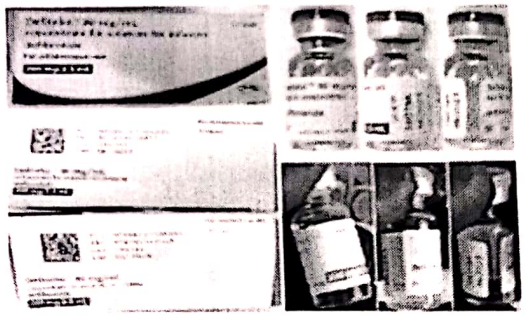
নং- ডিজিডিএ/ এলার্ট-নোটিশ/এমসি-১৬/২০১৯/ ৮৭৫০ তারিখঃ ২৭/০৪/২০২৩ খ্রীঃ

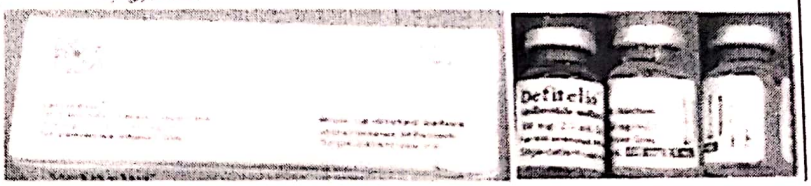
অফিস আদেশ

ঔষধ প্রশাসন অধিদপ্তরের মাঠ পর্যায়ের সকল কর্মকর্তাদের জানানো যাচ্ছে যে, বিশ্ব স্বাস্থ্য সংস্থা (WHO) সম্প্রতি মেডিক্যাল প্রোডাক্ট এলার্ট 3/2023 এ এই মর্মে সতর্ক করেছে যে, Gentium Srl কর্তৃক উৎপাদিত DEFITELIO 80mg/ml concentrate for solution for infusion এর একটি নকল ব্যাচ কিরগিজস্তান ও সংযুক্ত আরব আমিরাতের বাজারে পাওয়া যাচ্ছে। DEFITELIO 80mg/ml concentrate for solution for infusion এর আসল উৎপাদনকারী প্রতিষ্ঠান Gentium Srl জানিয়েছে যে, উল্লিখিত DEFITELIO 80mg/ml concentrate for solution for infusion এর লেবেলে প্রদর্শিত ব্যাচ নং, মেয়াদ উত্তীর্ণের তারিখ আলাদা। লেবেলে প্রদর্শিত প্যাকিং এর লেখায় বিভিন্ন ধরণের বৈসাদৃশ্য ও মুদ্রণে বিভিন্ন ধরণের ভুল রয়েছে।

Falsified মেডিক্যাল প্রোডাক্টের বর্ণনাঃ

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	

এমতাবস্থায় উল্লেখিত DEFITELIO vial টি বাজারে পাওয়া গেলে তা জব্দ করে প্রয়োজনীয় ব্যবস্থা গ্রহণের জন্য এতদ্বারা নির্দেশ প্রদান করা গেল।

২৭/০৪/২৩
মোঃ আসরাফ হোসেন
পরিচালক
ও
হেড অব মার্কেট সার্ভিল্যান্স এন্ড কন্ট্রোল
ঔষধ প্রশাসন অধিদপ্তর, ঢাকা।
ফোনঃ ০২২২২২-৮০৮০৩
মোবাইলঃ ০১৮১৯-১৪০৪২১

১. সংযুক্তিঃ ০২ (দুই) পাতা

World Health Organization

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.

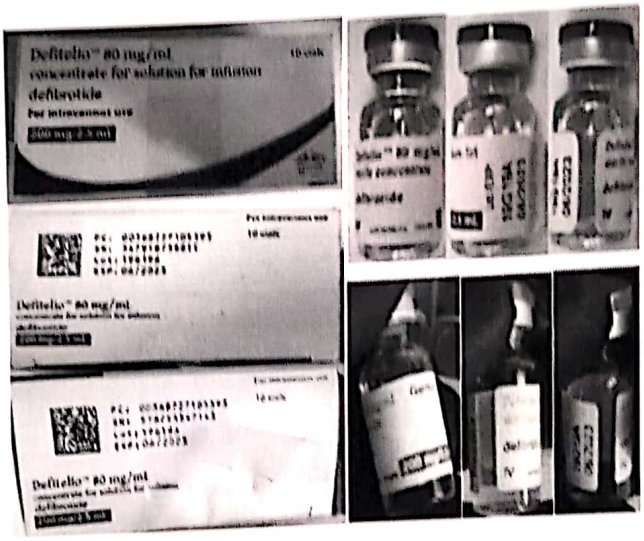
Healthcare professionals should report the incident to the National Regulatory Authorities/National Pharmacovigilance Centre. National regulatory/health authorities are advised to immediately notify WHO if they identify these falsified products.

If you have any information about the manufacture or supply of these products, please contact WHO via rapidalert@who.int.

World Health Organization

11 April 2023

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