# SAFETY ALERT

**DRAP SAFTEY ALERT NO. 15**

## SAFETY ALERT OF FALSIFIED AND CONTAMINATED DEFIBROTIDE IDENTIFIED IN WHO REGIONS OF WESTERN PACIFIC, EUROPE AND EASTERN MEDITERRANEAN.

**Date:** 4th of June, 2020

### Target Audience:

- Healthcare Professionals.
- Patients, consumers or caregivers.

### Problem or Issue:

World Health Organization (WHO) Global Surveillance and Monitoring System for Substandard and Falsified Medical Products through a Medical Product Alert No.5 /2020 have informed about confirmed falsified Defibrotide 200MG vials of 2.5ML (80MG/ML) concentrate for solution for infusion identified in Australia, Latvia and Saudi Arabia, sold under the brand name Defitelio. WHO informed that on 13th March, 8th April and 9th April, 2020 it was informed by stakeholders that falsified Defibrotide 200MG vials of batch number 0286 and 0126 have been identified/supplied in Australia, Saudi Arabia and Latvia. Laboratory analyses, conducted by national medicines regulatory authorities and the manufacturer of the genuine product, established that these falsified products do not contain any of the expected active ingredients. The solution in the vials is also contaminated with mould (Cladosporium sp. and Aspergillus niger).Information available to WHO indicates that both batches of falsified DEFIBROTIDE 200MG vials were present within the regulated supply chain in Latvia as early as January 2020 and were also handled by medicine wholesalers in the United Kingdom in February 2020. The genuine manufacturer of Defibrotide, GENTIUM S.R.L has also confirmed to WHO that they did not manufactured the falsified product. The manufacturers also informed that authentic Defibrotide 200mg vials with batch number 0286 were supplied to Argentina, Hong Kong, Malaysia, Singapore and Turkey and authentic Defibrotide 200MG vials with batch number 0126 were supplied to Australia, Jordan, Kuwait, Lebanon, New Zealand, Qatar, Singapore, Turkey and the United Arab Emirates.

### Therapeutic Goods Affected:

Name: **Falsified Defibrotide 200MG Vials OF 2.5ML (80MG/ML) Concentrate for Solution.**

| **Product name** | **DEFIBROTIDE 200MG VIALS OF 2.5ML (80MG/ML) CONCENTRATE FOR SOLUTION FOR INFUSION** | |
|---|---|---|
| **Stated manufacturer** | GENTIUM S.R.L | |
| **Batch number** | 0286 | 0126 |
| **Expiry date** | 09/2021 | 08/2021 |

## Advice for Patient, Healthcare Professionals and Other Stakeholders:-

Those patients, who possess the above falsified product, should not use it. If the patient has used the above mentioned falsified medical product, and has suffer an adverse event, should immediately seek the advice from a qualified healthcare professional, and ensure that they report the incident to Pakistan National Pharmacovigilance Centre, Drug Regulatory Authority of Pakistan. All drugs must be obtained from authentic and reliable sources. Their authenticity and condition should be carefully checked. Healthcare professionals are requested to ensure that necessary information related to the above falsified product are reported to them by the patient and is subsequently reported to the Pakistan National pharmacovigilance Centre, DRAP, Islamabad. Other concerned stakeholders are requested to take further necessary action on their part.

Both healthcare professionals and patients are requested to report any suspected adverse drug reaction to **Pakistan National Pharmacovigilance Centre,** Drug Regulatory Authority of Pakistan through **DRAP Med Vigilance E-reporting system** http//: https://primaryreporting.who-umc.org/Reporting/Reporter?OrganizationID=PK or at npc@dra.gov.pk.

For further details see the enclosures.

World Health Organization

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Ref. RPQ/REG/ISF/Alert N°5.2020 7 May 2020

# Medical Product Alert n°5/2020
# Falsified and contaminated Defibrotide identified in WHO regions of Western Pacific, Europe and Eastern Mediterranean

**This alert relates to falsified DEFIBROTIDE 200MG VIALS OF 2.5ML (80MG/ML) CONCENTRATE FOR SOLUTION FOR INFUSION identified in Australia, Latvia and Saudi Arabia. This product is sold under the brand name Defitelio.**

On 13 March 2020, the WHO Global Surveillance and Monitoring System on Substandard and Falsified (SF) Medical Products was informed that falsified DEFIBROTIDE 200MG vials were identified at patient level in Australia, displaying batch number 0286 (see Table 1 below for full details).

Following enquiries with stakeholders, on 8 April 2020, WHO was informed that falsified DEFIBROTIDE 200MG vials had also been supplied to Saudi Arabia, displaying batch number 0286 and 0126 (see Table 1 below for full details).

Following enquiries with stakeholders, on 9 April 2020, WHO was informed that falsified DEFIBROTIDE 200MG vials, displaying batch number 0126, had also been identified in Australia and Latvia.

DEFIBROTIDE is used to treat hepatic veno-occlusive disease, in which the blood vessels in the liver become damaged and obstructed by blood clots. This can be caused by treatments prior to a stem cell transplantation.

Laboratory analyses, conducted by national medicines regulatory authorities and the manufacturer of the genuine product, established that these falsified products do not contain any of the expected active ingredient. The solution in the vials is also contaminated with mould (Cladosporium sp. and Aspergillus niger).

Information available to WHO indicates that both batches of falsified DEFIBROTIDE 200MG vials were present within the regulated supply chain in Latvia as early as January 2020 and were also handled by medicine wholesalers in the United Kingdom in February 2020. It is important to note that widespread vigilance is required from all countries, regardless of where the product was originally identified.

*Table 1: falsified defibrotide subject of WHO Alert n°5/2020, identified in Australia, Latvia and Saudi Arabia*

| **Product name** | **DEFIBROTIDE 200MG VIALS OF 2.5ML (80MG/ML) CONCENTRATE FOR SOLUTION FOR INFUSION** | |
|---|---|---|
| **Stated manufacturer** | GENTIUM S.R.L | |
| **Batch number** | 0286 | 0126 |
| **Expiry date** | 09/2021 | 08/2021 |

The two products listed in Table 1 are confirmed falsified, on the basis that there is deliberate misrepresentation of their identity, composition and source.

The genuine manufacturer of Defibrotide, GENTIUM S.R.L has also confirmed to WHO that:

- They did not manufacture the above products.
- Authentic DEFIBROTIDE 200MG VIALS with batch number 0286 were supplied to Argentina, Hong Kong, Malaysia, Singapore and Turkey.
- Authentic DEFIBROTIDE 200MG VIALS with batch number 0126 were supplied to Australia, Jordan, Kuwait, Lebanon, New Zealand, Qatar, Singapore, Turkey and the United Arab Emirates.

For guidance and photographs, please refer to page 2 of this Alert n°5/2020.

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**Photos of Falsified DEFIBROTIDE Batch number: 0286, with expiry date: 09/2021**


Sample from Latvia

Sample from Latvia

**Photos of Falsified DEFIBROTIDE Batch number: 0126, with expiry date: 08/2021**


Sample from Australia

Sample from Australia

WHO requests increased vigilance within the supply chains of countries likely to be affected by these falsified products. Increased vigilance should include hospitals, clinics, health centres, wholesalers, distributors, pharmacies and any other suppliers of medical products.

If you are in possession of the above products, please do not use them. If you have used these falsified products, or if you suffer an adverse reaction/event having used these products, you are advised to seek immediate medical advice from a qualified healthcare professional, and to report the incident to the National Regulatory Authorities/National Pharmacovigilance Centre.

All medical products must be obtained from licensed, authorized and reliable sources. Their authenticity and condition should be carefully checked. Seek advice from a healthcare professional in case of doubt.

National regulatory/health authorities are advised to immediately notify WHO if these falsified products are identified in their country(ies). If you have any information concerning the manufacture, distribution, or supply of these products, please contact rapidalert@who.int .

**WHO Global Surveillance and Monitoring System**
**for Substandard and Falsified Medical Products**
For more information, please visit: www.who.int/medicines/regulation/ssffc/en/