PLEASE READ

IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA

An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Boehringer Ingelheim

Boehringer Ingelheim Ireland Limited, 4045 Kingswood Road, Citywest Business Campus, Co. Dublin, D24 VO6K, Ireland

Boehringer Ingelheim Ireland Limited

21 September 2022

Metalyse® (tenecteplase) 10000 units (50 mg) powder and solvent for solution for injection: temporary supply shortage

Your reference

Our reference

Dear Healthcare Professional,

Boehringer Ingelheim International GmbH (hereafter referred to as "BI") in agreement with the European Medicines Agency and the HPRA would like to inform you of the following:

4045 Kingswood Road,
Citywest Business Campus,
Co. Dublin,
D24 VO6K, Ireland
Telephone +353-1-2959620
www.boehringer-ingelheim.ie

Summary

- The current supply shortage of Metalyse on the EU market is foreseen to last into 2024.
- Mitigating efforts are being made against current supply interruptions in the short to long-term and regarding optimal use of available product to support supply in the interest of patients.
- Clinical use of available stock should be carefully managed to avoid unnecessary wastage; supplies should be stored appropriately.

Background on the supply shortage

Metalyse is indicated in adults for the thrombolytic treatment of suspected myocardial infarction with persistent ST elevation or recent left bundle branch block within 6 hours after the onset of acute myocardial infarction (AMI) symptoms.

The supply shortage is due to the rising number of patients eligible for the thrombolytic treatments and BI production capacity reaching its maximum.

BI is the marketing authorisation holder for the thrombolytic agents, Actilyse (alteplase) and Metalyse. Both thrombolytics are produced at a single manufacturing site in Biberach, Germany. The manufacturing process for these biopharmaceutical medicines is complex and cannot be further increased to meet the demand at short notice. The supply shortage is not related to a quality defect of the product or a safety issue.

Mitigation measures

- EMA will evaluate an extension of the shelf-life of Metalyse from 24 to 36 months. BI submitted relevant stability data to EMA at the end of August 2022
- BI has plans to increase manufacturing capacity for Metalyse by establishing an additional manufacturing site over the next three years.

Recommendations for HCPs

Ongoing shortages of thrombolytic agents continue to be a concern in all countries where Actilyse and Metalyse are marketed, including countries within Europe. Actilyse 10, 20 and 50 mg is an approved alternative thrombolytic treatment that can be used instead of Metalyse for acute myocardial infarction (STEMI). However, Actilyse is also subject to supply constraints and shortages in a number of markets due to manufacturing constraints, increased demand and the shift of prescriptions from Metalyse to Actilyse. Please note that Metalyse and Actilyse should be used within approved indications in eligible patients only.

Working together with HCPs, BI would like to support further actions to ensure equitable and efficient distribution of existing products. BI asks that clinical use of available stocks is carefully managed to avoid unnecessary wastage and supplies are stored appropriately.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, website: www.hpra.ie.

Adverse events should also be reported to Boehringer Ingelheim Drug Safety on 01 291 3960 or by emails to PV_local_uk_ireland@boehringer-ingelheim.com.

Company contact point

For access to further information, please contact Boehringer Ingelheim Medical Information on 01 295 9620 or email medinfo.bra@boehringer-ingelheim.com.

Yours faithfully

Dr. Christoph Zehendner
Medical Director (UK and Ireland)
Boehringer Ingelheim Ltd