Boehringer Ingelheim Limited · Ellesfield Avenue, Bracknell, Berkshire RG12 8YS

Boehringer Ingelheim Limited

14 October 2022

Metalyse® (tenecteplase) 10,000 units (50 mg) powder and solvent for solution for injection: temporary supply shortage

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Dear Healthcare Professional,

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

Summary

- The current supply shortage of Metalyse on the UK 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 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

- A shelf life extension for Metalyse from 24 months to 36 months has recently been agreed by the European Medicines Agency and an equivalent update will shortly be submitted to the MHRA for approval.
- 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.

Streptokinase is also indicated for acute STEMI initiated within 12 hours of symptom onset.

Indication: Acute myocardial infarction: within 12 hours of onset with persistent ST-segment elevation or recent bundle- branch block) and may be available as an alternative treatment to Metalyse.

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

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle▼

It is easiest and quickest to report ADRs online via the Yellow Card website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Adverse events should also be reported to Boehringer Ingelheim Drug Safety on +44 (0)1344 741436 or 0800 328 1627 or by email to PV_local_uk_ireland@boehringer-ingelheim.com.

Company contact point

For access to further information, please contact Boehringer Ingelheim Medical Information on 01344 742579 or email medinfo.bra@boehringer-ingelheim.com.

Yours faithfully,

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