

**Metalyse® (tenecteplase) 8000 units (40 mg) and 10000 units (50 mg) powder and solvent for solution for injection: temporary supply shortage**

Dear Healthcare Professional,

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

**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 is expected to submit relevant stability data to EMA at the end of August 2022.
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- 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.

*<Modify/Delete as needed in agreement with local authority: Treatment alternatives for Metalyse might be available: [list of alternative treatments as provided by local authority] >*

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.

### **Company contact point**

For access to further information, please contact [xxx]

Kind regards,

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*Signature\**

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| DHPC COMMUNICATION PLAN                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|---------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Medicinal product(s)/active substance(s)                                        | Metalyse 8000 units (40 mg), Metalyse 10000 units (50 mg)(tenecteplase)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Marketing authorisation holder(s)                                               | Boehringer Ingelheim International GmbH                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Safety concern and purpose of the communication                                 | Temporary supply shortage                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| DHPC recipients                                                                 | <p>Hospital Physicians and Hospital Pharmacists, only within those hospitals that have purchased at least 1 Metalyse pack since 01/2021. In case of lack of this information (eg countries that are selling through wholesalers), a decision at local level should be taken.</p> <p>Target recipients, include healthcare professionals involved in the prescribing and preparation of Metalyse within:</p> <ul style="list-style-type: none"><li>- Hospital Pharmacies</li><li>- Emergency Departments</li><li>- Cardiology Departments / Interventional cardiology</li><li>- Intensive Care Units</li></ul> |
| Member States where the DHPC will be distributed                                | EU/EEA countries where the product is marketed                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Timetable                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|                                                                                 | Date                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| DHPC and communication plan (in English) agreed by PRAC                         | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| DHPC and communication plan (in English) agreed by CHMP/CMDh                    | 26 Aug 2022                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Submission of translated DHPCs to the national competent authorities for review | Proposed 07 Sep 2022                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Agreement of translations by national competent authorities                     | Proposed 16 Sep 2022                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Dissemination of DHPC                                                           | Proposed 23 Sep 2022                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |