

Temporary supply interruption in Sweden

Subject:

Metalyse® (tenecteplase) 50 mg (10 000 IU) powder and solvent for solution for injection

Actilyse® 2 mg (alteplase) powder for solution for injection and infusion

Actilyse® (alteplase) 10 mg, 20 mg, 50 mg powder and solvent for solution for injection and infusion,

Dear Health Care Professional,

BI would like to inform you that, despite all efforts to further increase the production capacity for our BI Thrombolytics Actilyse® (alteplase) and Metalyse® (tenecteplase), BI currently expects temporary supply interruptions of Actilyse® 2mg (alteplase) and Metalyse® (tenecteplase) and a temporary drug shortage of Actilyse® (alteplase) 10 mg, 20 mg & 50 mg in several countries, including Sweden, in 2022 and 2023.

Indication

Metalyse® (tenecteplase) powder and solvent for solution for injection is registered for the thrombolytic treatment of acute myocardial infarction (AMI).

Alteplase® 2 mg (alteplase) powder for solution for injection is registered for the thrombolytic treatment of occluded central venous access devices including those used for haemodialysis.

Actilyse® (alteplase) 10 mg, 20 mg & 50 mg powder and solvent for solution for injection is registered for the thrombolytic treatment of acute myocardial infarction (AMI), the thrombolytic treatment in acute massive pulmonary embolism with hemodynamic instability and the thrombolytic treatment of acute ischaemic stroke.

The tight supply situation is due to a combination of the following factors:

- Due to the rising number of patients eligible for the Thrombolytics' treatment, the demand of our Thrombolytics is consistently increasing.
- At the same time, our production capacity is still limited. The Thrombolytics are produced solely at the Biberach site in Germany. Since the products are biopharmaceutical medicines with a complex manufacturing process, it is not possible to significantly expand production on short notice.
- Further, in the process of manufacturing new batches of Metalyse® for Q4-2021, BI experienced quality deviations, which resulted in a reduction of the expected output.
- In addition, there are other factors, such as a reduced yield in certain production campaigns, that have impacted the anticipated drug substance (DS) outputs.

It is foreseen that we might experience a supply interruption of Metalyse® (tenecteplase) and Actilyse 2 mg (alteplase) in Sweden starting as of Q2-Q3 2022 and a potential drug shortage of Actilyse® (alteplase) 10 mg, 20 mg & 50 mg in 2022-2023.

Currently the exact time of re-supply cannot yet be determined; Boehringer Ingelheim will inform you as soon as a date of product availability in Sweden is identified.

Based on our current assessment, we expect that the supply situation of our Thrombolytics remains constrained for the next two years on a global level.

Alternatives

Actilyse/Metalyse

The therapeutic alternative(s) available in the market are any other thrombolytic agent indicated and locally approved, or primary mechanical intervention for AMI eligible patients.

Thrombolysis should be prioritized for life threatening indications.

In case of limited availability of drug, a careful management of available stock is recommended, so to avoid disruption at patient level. Notably, attention should be taken on avoiding any wastage of drug, by using the most appropriate dosage strength available for each single patient.

Actilyse 2 mg

The therapeutic alternative(s) available in the market are any other thrombolytic agent indicated and locally approved, or the replacement of the venous access.

Boehringer Ingelheim is committed to patient care and regrets this situation. We continuously review the situation and will provide you with updates in case of any changes. Our teams are continuously working towards a solution to restore stocks of Actilyse® (alteplase) and Metalyse® (tenecteplase) to normal levels, in the shortest possible time and minimize the impact on patients.

Should you require any further information in the meantime, please do not hesitate to contact us.

Yours sincerely,

Michaela Sköld



Tendering & Contracting Manager

Boehringer Ingelheim AB

Phone: +46 (0) 705 89 48 23

E-mail: michaela.skoeld@boehringer-ingelheim.com