



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 December 2023
EMA/CHMP/562322/2023 Corr.¹
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion² (post authorisation)

Metalyse tenecteplase

On 14 December 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Metalyse. The marketing authorisation holder for this medicinal product is Boehringer Ingelheim International GmbH.

The CHMP adopted a new presentation and strength (5 000 units (25 mg) powder for solution for injection) together with a new indication for the thrombolytic treatment of acute ischaemic stroke in adults.

For information, the full indications for Metalyse will therefore be as follows:³

Metalyse 8 000 units (40 mg) powder and solvent for solution for injection and Metalyse 10 000 units (50 mg) powder and solvent for solution for injection:

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.

Metalyse 5 000 units (25 mg) powder for solution for injection:

Metalyse is indicated in adults for the thrombolytic treatment of acute ischaemic stroke (AIS) within 4.5 hours from last known well and after exclusion of intracranial haemorrhage.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

¹ 6 November 2024

² Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

³ New text in bold

