



23 September 2022
EMA/706012/2022 Rev.1¹

Shortage of Metalyse (tenecteplase) 8,000 units (40 mg) and 10,000 units (50 mg) powder and solvent for solution for injection	
Indication	Metalyse is used to treat adults suspected of having an acute myocardial infarction (heart attack) within six hours of the first symptoms appearing. It is used to dissolve the blood clots that have formed inside the blood vessels supplying the heart.
Reason for shortage	There has been an increase in demand for Metalyse due to a rise in the number of eligible patients, which cannot be met by the current manufacturing capacity. This has led to a supply shortage that is expected to last into 2025.
Member States affected²	All EU Member States where the product is currently marketed.
Monitoring of shortage	EMA's SPOC working party ³ is closely monitoring the supply situation and engaging with the marketing authorisation holder and other stakeholders to identify measures to mitigate the impact of the supply shortage (including the measures below). Summaries of the SPOC working party meetings can found on EMA's website .
Information to healthcare professionals	<ul style="list-style-type: none">• An increase in demand for Metalyse cannot be met by the current manufacturing capacity. This has led to a supply shortage that is expected to last into 2025.• A new manufacturing site will be set up over the coming years to increase the manufacturing capacity.• The shelf life of Metalyse has been extended from 24 to 36 months.• Healthcare professionals should use existing supplies in the most efficient way possible. This means using them

¹ The document was revised on 10 May 2023 to indicate that the shortage is expected to last into 2025 and to reflect ongoing monitoring by EMA's Medicines Shortages Single Point of Contact (SPOC) working party.

² This information may change. For up-to-date information about the status of a medicine shortage in a particular Member State, contact the [national competent authority](#).

³ The [SPOC working party](#) is responsible for monitoring and reporting events that could affect the supply of medicines in the EU.



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	<p>only for patients within the approved indications and avoiding unnecessary wastage.</p> <ul style="list-style-type: none"> • A direct healthcare professional communication (DHPC) has been sent to healthcare professionals in affected Member States. The DHPC is also available on the EMA website. • Additional advice, including information on alternatives, may be available from the national competent authority.
Information to patients	<ul style="list-style-type: none"> • The current manufacturing capacity for Metalyse cannot meet an increase in demand for this medicine. As a result, shortages have occurred. • A new manufacturing site will be set up in the coming years to increase the manufacturing capacity. • In the meantime, healthcare professionals have been asked to optimise use of supplies. • Your doctor may prescribe a suitable alternative. • Speak to your doctor or pharmacist if you have any questions. • Additional advice may be available from the national competent authority.
Status	Ongoing