



23 September 2022  
EMA/734545/2022 Rev.1<sup>1</sup>

**Shortage of Actilyse (alteplase)  
10, 20 and 50 mg powder and solvent for solution for injection and  
infusion and  
Actilyse Cathflo (alteplase)  
2 mg powder and solvent for solution for injection and infusion**

<b>Indication</b>	<p>Actilyse is used in adults for emergency treatment of acute myocardial infarction (heart attack), acute ischaemic stroke (stroke caused by failure of the blood supply to part of the brain) or acute pulmonary embolism (blood clot in blood vessels supplying the lung). It is used to dissolve the blood clots that have formed inside the blood vessels supplying the heart, brain or lungs.</p> <p>Actilyse Cathflo is used to dissolve blood clots that have formed in a patient's catheter, such as a dialysis catheter.</p>
<b>Reason for shortage</b>	<p>There has been an increase in demand for Actilyse 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.</p>
<b>Member States affected<sup>2</sup></b>	<p>All EU Member States where the product is currently marketed.</p>
<b>Monitoring of shortage</b>	<p>EMA's <a href="#">SPOC working party</a><sup>3</sup> 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).</p> <p>Summaries of the SPOC working party meetings can found on <a href="#">EMA's website</a>.</p>

<sup>1</sup> 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 and additional measures to maintain supply.

<sup>2</sup> 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](#).

<sup>3</sup> 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><b>Information to healthcare professionals</b></p>	<ul style="list-style-type: none"> <li>• An increase in demand for Actilyse cannot be met by the current manufacturing capacity. This has led to a supply shortage that is expected to last into 2025.</li> <li>• The marketing authorisation holder is taking steps to increase production of Actilyse in the short and long term.</li> <li>• Production of Actilyse Cathflo has been temporarily halted so that the alteplase active substance can be used for other strengths, to prioritise its use as emergency treatment for acute myocardial infarction, acute ischaemic stroke and acute pulmonary embolism.</li> <li>• A new manufacturing site will also be set up over the coming years to increase the manufacturing capacity.</li> <li>• Additional measures are being taken to increase availability of alteplase. These include the distribution of Actilyse batches manufactured under a previously approved process and the one-time donation of alteplase vials by another company that markets this product in North America.</li> <li>• Healthcare professionals should use existing supplies in the most efficient way possible. This means using them only for patients within the approved indications and avoiding disposal of unused supplies. A <a href="#">letter</a> has been sent by the marketing authorisation holder to healthcare professionals in the affected EU Member States.</li> <li>• Additional advice, including information on alternatives, may be available from the <a href="#">national competent authority</a>.</li> </ul>
<p><b>Information to patients</b></p>	<ul style="list-style-type: none"> <li>• The current manufacturing capacity for Actilyse cannot meet an increase in demand for this medicine. As a result, shortages have occurred.</li> <li>• The company that markets Actilyse is taking steps to increase the manufacturing capacity in the short and long term.</li> <li>• A new manufacturing site will be set up in the coming years to further increase the manufacturing capacity.</li> <li>• Additional measures are being undertaken to increase the availability of alteplase.</li> <li>• In the meantime, healthcare professionals have been asked to prioritise use for heart attacks, stroke and pulmonary embolism. This means that production of Actilyse Cathflo for use to unblock catheters has been</li> </ul>

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	<p>temporarily stopped.</p> <ul style="list-style-type: none"><li>• Your doctor may prescribe a suitable alternative.</li><li>• Speak to your doctor or pharmacist if you have any questions.</li><li>• Additional advice may be available from the <a href="#">national competent authority</a>.</li></ul>
<b>Status</b>	Ongoing