

Medication Safety Alert

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Issued by the Office of the Chief Pharmacist, SA Health
www.sahealth.sa.gov.au/medicationsafety



A patient **Safety Alert** advises of safety matters needing **immediate attention and mandatory action** to address high risk safety problems.

We recommend you inform:

- Executive Directors Medical Services
- Heads of Units
- General Managers
- Pharmacy Directors
- Medical Directors
- Clinical Directors
- Nursing Directors
- Drug and Therapeutics Committees
- Medication Safety Committees
- Safety and Quality Units
- Clinical Governance

Contact details:

T: (08) 8204 1944
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Tenecteplase (Metalyse®) - shortage update and conservation strategies

Background

There is a global shortage of tenecteplase (Metalyse®) that is predicted to extend **over the next 18 months**. During the shortage, there will be critical limitations on availability of tenecteplase.

All endeavours are being made to maintain supplies including purchase of overseas registered products, however it is expected that global demand will be high and conservation strategies are needed to ensure priority for treatment where no alternatives exist.

Priority use and conservation of tenecteplase (Metalyse®) and transition to alteplase (Actilyse®)

Existing tenecteplase supplies must be prioritised for patients and settings where there are no alternatives.

SA Health sites and clinicians are required to adopt conservation strategies for tenecteplase *and* to implement prioritisation strategies for transitioning to alteplase (Actilyse®) in accordance with the recommendations below. These recommendations have been co-developed by key clinicians, clinical groups and representative stakeholders.

For immediate implementation

1. Alternative thrombolytics (i.e. urokinase*) must be used for management of:
 - > peripheral arterial thromboembolism (arterial or catheter-directed thrombolysis)
 - > restoring vascular access patency

[*available via the TGA special access scheme]
2. Do not discard expired stock of tenecteplase (Metalyse®). The TGA has approved a 12-month shelf-life extension for certain batches. Refer to [Medication Safety Notice No. SA 02/2022](#) or the [TGA website](#) for information about the extended shelf-life for these products.
3. Develop local procedures for labelling and storage of un-used tenecteplase if administered for stroke thrombolysis (e.g. where less than a full syringe is used).

Develop a plan now and implement from 1 October 2022

1. Prioritise use of tenecteplase for:

August 2022

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- non-metropolitan and remote area thrombolysis for STEMI (e.g. ICCnet, RFDS)
- patients presenting with acute myocardial infarction that are more than one hour away from receiving percutaneous coronary intervention (PCI).
This includes:
 - > Rural and remote facilities/hospitals
 - > Aboriginal health services.
- 2. Tenecteplase is reasonable to administer:
 - > for acute ischaemic stroke in telestroke centres where alteplase cannot also be stocked, and
 - > large vessel occlusion patients transferring emergently for thrombectomy, where administering alteplase would impede transfer.

Action required by SA Health services and staff

1. Ensure that all relevant clinicians, committees, hospital and clinical services staff are aware of this notice and the clinical recommendations for priority use of tenecteplase during the shortage
2. Develop and implement the necessary action plans to conserve and prioritise the use of tenecteplase immediately, and from 1 October 2022 transition to alteplase for non-prioritised indications.
3. Local Health Networks and clinical services are to work with SA Pharmacy to continue monitoring stock levels and use of tenecteplase, alteplase and other lytic agents.
4. Monitor the [TGA website](#) for further updates about clinical guidelines and any further recommended conservation measures.

Further information

The TGA has approved the temporary supply of overseas-registered equivalent tenecteplase products under section 19A of the *Therapeutic Goods Act 1989* and SA Pharmacy is working to procure these products.

SA Health and the TGA continue to work together to monitor the supply of tenecteplase and will work with stakeholders to update this advice as required.

Refer to [Medication Safety Notice No. SA 02/2022](#) and the [TGA website](#) for information about the shortage of tenecteplase. The [South Australian Medicines Formulary](#) will be updated in line with these recommendations.

For any enquiries or concerns, please contact your service pharmacist or pharmacy department directly; or email HealthMedicationSafety@sa.gov.au