

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:

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Tenecteplase (Metalyse®) shortage Implementation of restrictions to conserve supply from 5 October 2022

Background

The global shortage of tenecteplase (Metalyse®) is predicted to extend **over the next 18 months** which places critical limitations on stock availability.

All endeavours are being made to maintain supplies including purchase of overseas products, however conservation strategies are needed to ensure access where no alternatives exist.

The following measures have been developed in collaboration with cardiology and stroke clinicians and LHN representatives and are based on TGA recommendations.

Priority use and conservation of tenecteplase

From **Wednesday 5 October 2022** all public hospitals and health services must implement the following restrictions on use of tenecteplase.

Use of tenecteplase is restricted to:

- 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 and Aboriginal health services;
- acute ischaemic stroke thrombolysis in regional hospitals (supervised by the SA Telestroke service);
- ischaemic stroke large vessel occlusion thrombolysis preceding emergent transfer within Adelaide for thrombectomy

Where tenecteplase is used, clinicians must be alerted to differences with the overseas approved product. Education resources about the overseas approved products stocked can be found [here](#).

For immediate implementation by LHNs and health services

1. Review clinical protocols and guidelines which include tenecteplase; ensure these are updated if required and ready for the transition to priority use from Wednesday 5 October 2022.
2. Review imprest holdings/locations and stock ordering to reflect the change in use and agreed priorities. Ensure appropriate imprest or shelf labelling to reflect the restricted indications.



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3. Ensure an approval process for any critical use outside of the priority indications is in place.
4. Implement local procedures for labelling and storage of any un-used tenecteplase if administered for stroke thrombolysis (e.g., where less than a full vial is used).
5. Use alteplase or alternate thrombolytic agents for all other indications
6. Implement the purchase of alteplase and alternative thrombolytic agents.

Ongoing action required by all LHNs, SA Health services and staff

1. Ensure that all relevant clinicians, committees, hospital and clinical services staff are aware of this notice and the priority use of tenecteplase and use of alternative agents during the shortage.
2. Do not discard expired stock of tenecteplase (Metalyse®). The TGA has approved a 12-month shelf-life extension for certain batches. Refer to the [TGA website](#) for information about the extended shelf-life for these products.
3. Work with SA Pharmacy to continue monitoring stock levels and use of tenecteplase, alteplase and other thrombolytic agents.

Further information

Monitor the [TGA website](#) for further updates about clinical guidelines and any further recommended conservation measures.

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](#), [Medication Safety Alert 02/2022](#) and the [TGA website](#) for information about the shortage of tenecteplase.

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



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