

Medication Safety Notice

No. SA 02 / 22 page 1 of 2

Issued by the Office of the Chief Pharmacist, SA Health

www.sahealth.sa.gov.au/medicationsafety



A patient **Safety Notice** strongly advises the implementation of recommendations or solutions to improve quality and safety.

We recommend you inform:

- 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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Safety@sa.gov.au

Tenecteplase (Metalyse®)

Global shortage and shelf-life extension

Background

- > Tenecteplase is a thrombolytic used to dissolve blood clots in the immediate period following a heart attack, stroke or pulmonary embolism, used in admitted patients and ambulance settings.
- > There is an imminent **global shortage** of 40mg and 50mg tenecteplase injection that is predicted to extend over the next 18 months. The shortage is due to manufacturing capacity constraints following increases in global demand.

Immediate action required by SA Health staff and services

1. Note the global shortage of tenecteplase that is predicted to extend over the next 18 months.
2. **Do not to discard tenecteplase (Metalyse®) stock that is expiring end of July 2022 and November 2022.**
3. Ensure a check of product expiry dates and batch numbers is undertaken and where appropriate changes to packaging/ labelling to reflect the **extended shelf life** for these products as per TGA recommendations below:

Medicine name	Batch number	Original (Printed) expiry date	Extended expiry date
METALYSE tenecteplase (rch) 40mg powder for injection vial plus prefilled syringe (ARTG 75012)	007057	31/07/2022	31/07/2023
	101396	30/11/2022	30/11/2023
METALYSE tenecteplase (rch) 50mg powder for injection vial plus prefilled syringe (ARTG 75013)	006382	31/07/2022	31/07/2023
	101397	30/11/2022	30/11/2023

Further Information

- > The Therapeutic Goods Administration (TGA) has published a [web statement](#) providing information about the shortage and extending the shelf life of specified batches.
- > The TGA is working closely with the manufacturer, Boehringer Ingelheim (BI), clinical experts and Chief Pharmacists to monitor current stock levels, evaluate the likely impact of this shortage and implement a range of conservation strategies and contingencies.

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- > Conservation management strategies and clinical guidelines developed in collaboration with clinical experts will be published shortly.

Further contingency

- > In addition to extending the shelf life of tenecteplase, the TGA has approved the supply of two overseas-registered equivalent products under section 19A of the *Therapeutic Goods Act 1989*, to minimise the public health impact of this shortage.
 - TKNASE tenecteplase 50mg powder for solution kit (USA); and
 - TNKASE tenecteplase 50mg powder for solution kit (Canada)

Monitoring

SA Pharmacy will continue to monitor tenecteplase stock levels at SA Health sites in accordance with conservation management strategies.

Further actions

1. Ensure all relevant clinicians/committees and services are aware of this notice.
2. Implement the recommended check and extension of tenecteplase expiry dates – **do not discard product that is reaching expiry**.
3. Local Health Networks and Clinical Networks should work with SA Pharmacy to monitor stock levels of tenecteplase and implement relevant strategies.
4. Monitor the [TGA website](#) for further updates about clinical guidelines and any further recommended conservation measures.

Further enquiries

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



Government
of South Australia
SA Health

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