Safety Alert 005/22

Issue date
1 September 2022

Distributed to:
Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:
Chief Executives
Directors of Clinical Governance

We recommend you also inform:
- Drug and Therapeutics Committees
- Directors of Medical Services
- Directors of Pharmacy
- Directors of Nursing
- Directors and Managers of
  - Cardiac Catherisation Laboratories
  - Cardiology
  - Emergency
  - Neurology

NSW Ambulance

Deadline for completion of action – see actions

Expert Reference Group
Content reviewed by:
- Chief Pharmacist U
- ACI Cardiac Ne ork
- ACI Stroke Ne ork
- Emergency Ca Institute
- NSW Ambulance
- HealthShare NSW

State Preparedness and Response Unit

Clinical Excellence Commission
Tel: 02 9269 5500
Email
Internet Website
Intranet Website

Review date
December 2023

Critical disruption to supply – tenecteplase (Metalyse®) injection – UPDATED

This is a revision of SA004/22 with amended wording to align with TGA Joint Statement regarding the shortage of tenecteplase.

Situation

There is a critical disruption to the supply of tenecteplase (Metalyse®) 40 mg and 50 mg powder for injection vials, which is exp cted to continue until the end of 2023. Intermittent supply will be available, oweve will not be sufficient to meet normal demand. The disruption is du to manufacturing capacity constraints following increases in global de and.

Metalyse® injection is the only tenect pla e produc egistered for use in Australia. It is approved for the thrombolytic t atment of the acute phase of myocardial infarction.

Need for urgent stock prese tion a oss NSW Health and alternative supply

Stock preservation strat ies are to be implemented by LHDs, SHNs and NSW Ambulance i diat ly to educe the risk of stock being exhausted. Alteplase stock levels ave en increased to accommodate a surge in usage. Despi e this, us ge of both agents should be judicious and appropriate.

The Therapeutic Go ds Administration (TGA) has approved Boehringer Ingel eim t extend the shelf-life of certain batches of Metalyse® by 12 month noting n change to the efficacy or safety of the therapy. Refer to the TGA alert for etails and ensure stock is appropriately re-labelled by the Ph cy Service to reflect the updated expiry date. NSW Health is aware t at the are other batches in circulation with short expiry dates. **Out of date enect plase should not be disposed of, pending further decisions on e y date extension by the TGA.** This stock should be returned to a NSW Health Pharmacy Department or Ambulance service hub for quarantined storage.

The TGA have approved the supply of two overseas-registered products under section 19A (S19A) of the Therapeutic Goods Act 1989 – TNKase from USA and Canada. The S19A alternatives contain a water for injection vial from which the diluent must be drawn up prior to reconstitution of the tenecteplase injection. This differs from Metalyse® which contains a pre-filled syringe of water for injection. The S19A alternatives also include a TwinPak® Dual Cannula Device in the box, which clinicians may not be familiar with. Clinicians should be alerted to these differences if S19A alternatives are used. Education resources can be found here.

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Clinical and governance recommendations and conservation strategies

- Drug and Therapeutics Committees (DTCs) must ensure that a process is in place to preserve remaining supplies of tenecteplase.
- **Supply of tenecteplase must be prioritised for indications where alternatives are not available or cannot be used:**
  - pre-hospital thrombolysis (e.g., ambulance services)
  - small rural and remote facilities/hospitals (e.g., use as nurse-administered thrombolysis).
- Alteplase should be used in metropolitan and larger regional hospitals to conserve tenecteplase for the above listed settings.
- Wastage should be minimised by using the most appropriate product (40 mg or 50 mg) based on the required dose of tenecteplase.
- Remove tenecteplase from imprest in areas other than Emergency Departments. Provisions must be in place for timely access to this medicine outside of normal Pharmacy operating hours.
- Remind clinicians that use of tenecteplase outside the indication listed in TGA approved Product Information is "off-label". Off-label use (for example use of tenecteplase for ischaemic stroke via the intravenous or intra-arterial route, the management of massive pulmonary embolism or in a clinical trial setting) must be closely monitored by DTCs and minimised during the disruption to supply.

Required actions for the Local Health Districts/Networks

1. **Immediately upon receipt**, distribute this updated Safety Alert to all relevant clinicians, clinical departments and committees.
2. **Within 24 hours**, acknowledge receipt of this Safety Alert and confirm distribution.
3. Ensure tenecteplase stock subject to a shelf life extension is re-labelled by the Pharmacy Service with the revised expiry date and quarantine batches of out-of-date tenecteplase not addressed by the recent TGA alert pending further advice.
4. Report any incidents related to this disruption to supply in the local incident management system.
5. Escalate concerns that are not able to be managed locally to: CEC-MedicationSafety@health.nsw.gov.au