



ProPharmaceuticalsGroup

Pro Pharmaceuticals Group Pty LTD

ABN: 20 605 457 430

www.propg.com.au

Dear Healthcare Professional,

Shortage of METALYSE tenecteplase (rch) 50mg powder for injection vial plus prefilled syringe (ARTG 75013) and alternate supply arrangement under Section 19A of the Therapeutic Goods Act

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you the change in supply status of METALYSE tenecteplase (rch) 50mg powder for injection vial plus prefilled syringe in Australia.

The Australian registered medicine, METALYSE tenecteplase (rch) 50mg powder for injection vial plus prefilled syringe AUST R: 75013 sponsored by Boehringer Ingelheim Pty Ltd is currently in shortage.

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **TNKASE tenecteplase 50mg powder for solution kit (USA)**. This product is NOT registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under section 19A of the Therapeutic Goods Act 1989 until **31st January 2024** for the following indication(s):

METALYSE is indicated for the thrombolytic treatment of the acute phase of myocardial infarction. Treatment should be initiated as soon as possible after the onset of symptoms. Treatment can be initiated within 12 hours of symptom onset.

TNKASE tenecteplase 50mg powder for solution kit (USA) is registered and marketed in USA by **Genentech, Inc.**

Reconstitution of the s19A product is different to the ARTG product. Please refer to the Summary of Product Characteristics (SmPC) for reconstitution instructions of TNKASE.

Pro Pharmaceuticals Group recommends that healthcare professionals refer to the Australian approved Product Information for recommended dosing.

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with **TNKASE tenecteplase 50mg powder for solution kit (USA)** must be reported by healthcare professionals, pharmacists, and patients to the TGA at <https://www.tga.gov.au/reporting-problems> or to Pro Pharmaceuticals Group on 1300077674 or email regulatory@propg.com.au

Any product complaints with **TNKASE tenecteplase 50mg powder for solution kit (USA)** should be reported to Pro Pharmaceuticals Group on 1300 077674 or email regulatory@propg.com.au

For any orders please contact Pro Pharmaceuticals Group on 1300077674 or email info@propg.com.au

Please forward this information to relevant staff members in your organisation.

For further information, please contact Pro Pharmaceuticals Group on 1300077674 or email info@propg.com.au

Sincerely,

Sandip Manku – Director Pro Pharmaceuticals Group



QR code link to SmPC (Product Information)