ProPharmaceuticalsGroup

Pro Pharmaceuticals Group Pty LTD
ABN: 20 605 457 430
www.propg.com.au

Dear Healthcare Professional,

Shortage of Actilyse alteplase (rch) 50mg powder for injection vial with diluent vial (ARTG 17905)

Pro Pharmaceuticals Group recognises the importance of supplying essential medicines in Australia and would like to advise you the change in supply status of Actilyse alteplase (rch) 50mg powder for injection vial with diluent vial in Australia.

The Australian registered medicine Actilyse alteplase (rch) 50mg powder for injection vial with diluent vial (ARTG 17905) sponsored by Boehringer Ingelheim Pty Ltd is currently in shortage due to unexpected increase in demand due to the shortage of Metalyse (tenecteplase).

Pro Pharmaceuticals Group has arranged for the supply of an alternative product, **ACTIVASE® rt-PA alteplase for injection, Lyophilized powder for injection - 100 mg (Canada)**. 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 from 1st January 2023 until 31st January 2024 for the following indication(s):

ACTIVASE rt-PA (alteplase for injection) is indicated for:

- *The lysis of suspected occlusive coronary artery thrombi associated with evolving transmural myocardial infarction. Treatment should be initiated as soon as possible after the onset of acute myocardial symptoms.*
- *The management of acute ischemic stroke (AIS) in adults for improving neurological recovery and reducing the incidence of disability. Treatment should only be initiated within 3 hours after the onset of stroke symptoms, and after exclusion of intracranial hemorrhage by a cranial computerized tomography (CT) scan or other diagnostic imaging method sensitive for the presence of hemorrhage.*

ACTIVASE® rt-PA alteplase for injection, Lyophilized powder for injection - 100 mg (Canada) is registered and marketed in CANADA by **Roche Canada**

There are two separate Canadian product monographs' attached. Healthcare professionals should refer to these for reconstitution and recommended dosing instructions.

A comparison table of differences between is given below:

	ARTG product (Actilyse alteplase (rch) 100mg powder for injection vial with diluent vial (ARTG 17905))	**S19A product (ACTIVASE® rt-PA alteplase for injection, Lyophilized powder for injection - 100 mg (Canada))**
Indication	***Myocardial Infarction*** • *ACTILYSE is indicated for intravenous use in adults for the lysis of suspected occlusive coronary artery thrombi associated with evolving transmural myocardial infarction. Treatment should be initiated as soon as possible after the onset of symptoms. The treatment can be initiated within 12 hours of symptom onset.* ***Pulmonary Embolism*** • *ACTILYSE is also indicated in patients with acute massive pulmonary embolism in whom thrombolytic therapy is considered appropriate.* ***Acute Ischaemic Stroke*** • *ACTILYSE is indicated for thrombolytic treatment of acute ischaemic stroke. Treatment must be started as early as possible within 4.5 hours after onset of stroke symptoms and after exclusion of*	*ACTIVASE rt-PA (alteplase for injection) is indicated for:* • *The lysis of suspected occlusive coronary artery thrombi associated with evolving transmural myocardial infarction. Treatment should be initiated as soon as possible after the onset of acute myocardial symptoms.* • *The management of acute ischemic stroke (AIS) in adults for improving neurological recovery and reducing the incidence of disability. Treatment should only be initiated within 3 hours after the onset of stroke symptoms, and after*

	intracranial haemorrhage by appropriate imaging techniques (e.g. cranial computerised tomography or other diagnostic imaging method sensitive for the presence of haemorrhage). The treatment effect is time-dependent; therefore earlier treatment increases the probability of a favourable outcome.	*exclusion of intracranial hemorrhage by a cranial computerized tomography (CT) scan or other diagnostic imaging method sensitive for the presence of hemorrhage.*
Excipients	Arginine, nitrogen, phosphoric acid and polysorbate 80	L-arginine, phosphoric acid and polysorbate 80

Reporting suspected adverse events is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with ACTIVASE® rt-PA alteplase for injection, Lyophilized powder for injection - 50 mg (Canada) 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 **ACTIVASE® rt-PA alteplase for injection, Lyophilized powder for injection - 100 mg (Canada)** 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 orders@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 to Product Information Acute Ischemic Stroke Indication	QR Code to Product information Acute Myocardial Infarction Indication