Temporary Medicine Shortage of Metalyse (tenecteplase)

14 December 2020

Dear Healthcare Professional,

Boehringer Ingelheim would like to inform you about a temporary medicine shortage of Metalyse (tenecteplase) 50mg powder and solvent for injection, registered for the thrombolytic treatment of acute myocardial infarction (AMI)[1].

The temporary medicine shortage is due to a combination of factors:

- complex production including limitation of manufacturing capacity
- a significant increase in global demand for Metalyse.

Based on current use patterns in New Zealand, the estimated start of the supply interruption of Metalyse is April 2021. At this point in time re-supply is expected in late 2021. Where appropriate, please consider the use of alternate patient pathways and treatments, for example PCI services.

The therapeutic alternative available for the treatment of acute myocardial infarction (AMI) in the market is Actilyse (alteplase), powder and solvent for solution for injection.*[2]

In close partnership with stakeholders across the New Zealand health community, Boehringer Ingelheim is working to carefully manage the allocation of supply of Metalyse to areas of highest need where alternative treatments are not possible, for example ambulance service and rural/provincial hospitals.

Boehringer Ingelheim is closely monitoring the supply situation in New Zealand and cannot support excess stockpiling of Metalyse.

Boehringer Ingelheim strongly recommends that Metalyse is used only according to the current approved indication for acute myocardial infarction (AMI).[1]

Actilyse is the only approved thrombolytic for the treatment of acute ischaemic stroke.[2]

We would like to remind you to please report any suspected adverse events to the Centre for Adverse Reactions Monitoring (CARM) https://nzphvc.otago.ac.nz/reporting/ .

Boehringer Ingelheim is committed to patient care and it is for that reason that we wanted to keep you informed and thank you in advance for your cooperation in working with us to appropriately manage this situation over the coming months.

*It is important to note that dosage differs by indication. Please refer to the full Actilyse (alteplase) Data Sheet for dosing instructions for each indication.

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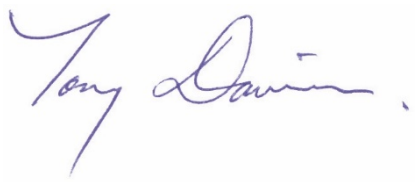
I would like to assure you that our teams are making every effort and are continuously working towards a solution to restore stocks of Metalyse to normal levels in the shortest possible time.

Should you require any further information, please do not hesitate to contact me directly.



Tony Davison
Business Unit Manager
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REFERENCES

1. **METALYSE (tenecteplase) New Zealand Data Sheet (3 December 2018)**

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

2. **ACTILYSE (alteplase) New Zealand Data Sheet (14 February 2019(**

   Approved Indications
   Acute Myocardial Infarction
   ACTILYSE is indicated for fibrinolytic therapy in acute thrombotic artery occusion to restore coronary artery patency, reduce infarct size, preserve ventricular function, prevent cardiac insufficiency and reduce mortality.
   - 90 minutes (accelerated) dose regimen (see section 4.2): for patients in whom treatment can be started within 6 h of symptom onset;
   - 3 hour dose regimen (see section 4.2): for patients in whom treatment can be started between 6 – 12 hrs after symptom onset.

   Acute Massive Pulmonary Embolism
   ACTILYSE is also indicated in patients with acute massive pulmonary embolism accompanied by haemodynamic instability.

   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 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.