Metalyse® (25 mg)

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about being given this medicine, speak to your doctor.

1. Why am I being given Metalyse?

Metalyse contains the active ingredient tenecteplase. Metalyse is used in adults to treat stroke caused by a blood clot in an artery of the brain (acute ischaemic stroke).

For more information, see Section 1. Why am I being given Metalyse? in the full CMI.

2. What should I know before I am given Metalyse?

You should not be given Metalyse if you have ever had an allergic reaction to Metalyse or any of the ingredients listed at the end of the CMI.

Tell your doctor or nurse if you have any current or previous medical conditions including recent bleeding, are at increased risk of bleeding or have blood clotting problems, blood vessel problems, high blood pressure, liver disease, a stomach ulcer, have had recent major injury/trauma, medical procedure (such as a biopsy or injection) or surgery.

Talk to your doctor if you take any other medicines, are pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given Metalyse? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Metalyse and affect how it works.

Tell your healthcare professional if you are taking any blood-thinning medicines or medicines to prevent blood clots (antiplatelets or anticoagulants), medicine to treat high blood pressure and some other heart conditions (Angiotensin Converting Enzyme Inhibitors) or any other medicines.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How will I be given Metalyse?

Metalyse will be prepared and administered to you by your doctor or by a healthcare professional as soon as possible after the start of your symptoms.

More information can be found in Section 4. How will I be given Metalyse? in the full CMI.

5. What should I know while being given Metalyse?

Things you should do	• Follow all instructions given to you by your healthcare professionals • Avoid moving unnecessarily after receiving Metalyse to prevent bleeding or bruising

For more information, see Section 5. What should I know while being given Metalyse? in the full CMI.

6. Are there any side effects?

There is an increased probability of getting side effects if you are over 80 years of age.

The most common side effect is bleeding more easily than usual, either inside the body, on the surface, or at the injection site.

Side effects that require urgent medical attention include: bleeding or blood clot within the head or brain which includes symptoms such as difficult or slurred speech, weakness in arms or legs, loss of memory or seizures; bleeding from the skin, nose, eyes or back passage; blood in the urine; coughing up blood; low blood pressure; nausea; vomiting; allergic reaction which includes symptoms such as shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin; fever.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Metalyse® (25 mg)

Active ingredient: tenecteplase

Consumer Medicine Information (CMI)

This leaflet provides important information about Metalyse. **You should also speak to your doctor if you would like further information or if you have any concerns or questions about being given Metalyse.**

Where to find information in this leaflet:

1. Why am I being given Metalyse?

Metalyse contains the active ingredient tenecteplase. It belongs to a group of medicines called tissue plasminogen activators (t-PA).

Metalyse is used in adults to treat stroke caused by a blood clot in an artery of the brain (acute ischaemic stroke).

It works by dissolving clots in the blood vessels. These clots cause disease by interfering with normal blood flow.

2. What should I know before I am given Metalyse?

Warnings

You must not be given Metalyse if you:

- are allergic to tenecteplase, gentamicin (a trace residue from the manufacturing process) or any of the ingredients listed at the end of this leaflet
- have had an acute ischaemic stroke that did not result in significant neurological impairment.

Because of the risk of bleeding, Metalyse should not be given to you if you have, or have had:

- any signs or symptoms of bleeding in the brain or skull
- a bleeding disorder at present or within the past 6 months, or a known tendency to bleed
- bleeding inside your body that cannot be stopped by applying pressure
- treatment with medicines used to dissolve blood clots (thrombolytic agent) or an anti-clotting agent (anticoagulant) such as warfarin, unless its effect has had time to wear off
- any history of damage to your brain or spinal cord such as a tumour, aneurysm (swelling and weakening of part of a blood vessel) or surgery on your brain or spine
- a tear in the inner layer of the main artery supplying blood from your heart, causing blood to leak between the layers
- very high and uncontrolled high blood pressure (hypertension)
- heart and lung resuscitation (CPR) in the past 2 weeks
- severe liver disease
- a stomach ulcer
- aneurysms (swelling and weakening of part of a blood vessel) in your arteries and/or known structural abnormalities in your arteries or veins
- tumours in which the risk of bleeding is increased
- swelling of the lining that surrounds the heart
- inflammation of the lining of the heart caused by bacteria
- inflammation of the pancreas
- experienced the symptoms of your stroke for more than 4.5 hours

Metalyse should be used with caution, with your doctor carefully evaluating the risks and benefits under the following conditions:

- if you weigh less than 60 kg
- if you are over 80 years of age
- if you had a very severe stroke
- if you experienced fits or seizures at the onset of your stroke
- if you have a recent history of previous stroke or serious head or spinal injury/trauma
- if you have stroke symptoms that are rapidly improving before receiving Metalyse
- if you have a low platelet count (platelets are blood cells involved in blood clotting)
- if you have very low sugar levels (under 2.7 mmol/L) or very high sugar levels (over 22.2 mmol/L) in your blood, which must be corrected before treatment with Metalyse.

Check with your doctor if you:

- have or have had any of the following medical conditions:
  - a previous stroke caused by a blood clot or a transient ischaemic attack (TIA) in the last 6 months
  - bleeding or clotting problems
  - recent bleeding from your stomach, gut or genitals
  - problems with your blood, especially if you also have severe liver or kidney disease
  - heart problems or high blood pressure
  - a family history of bleeding disorders
  - recent childbirth
  - recent medical procedure such as a biopsy, injection or surgery to any part of your body

- have allergies to any other medicines, foods, preservatives or dyes
- take any medicines for any other condition

Speak to your doctor if you are uncertain as to whether any of these conditions apply to you.

In addition, before starting treatment, your doctor will assess other factors which may increase the risks of using Metalyse. These include infected veins and cannula sites or any condition in which bleeding is a significant risk or would be particularly difficult to manage because of its location.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

Children

Metalyse must not be given to a child under the age of 18 years. The safety and effectiveness in this age group has not been established.

3. What if I am taking other medicines?

Tell your doctor if you are taking any other medicines, including any vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Metalyse and affect how it works. These include:

- Antiplatelets such as aspirin and anticoagulants such as heparin and warfarin or any other medicines used to "thin" the blood and prevent blood clots
- Angiotensin Converting Enzyme (ACE) inhibitors, a group of medicines used to treat high blood pressure and some other heart conditions

Check with your doctor if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Metalyse.

4. How will I be given Metalyse?

How much you will be given

The recommended dose for the treatment of acute ischaemic stroke is based on your body weight and ranges between 15 mg and 25 mg. The dose is given as a single injection over 5 to 10 seconds.

Your doctor may prescribe a different dose or duration of treatment to that described here.

Ask your doctor if you want more information.

How will you be given Metalyse

Metalyse will be given under the supervision of a doctor and in a setting where appropriate equipment is readily available for diagnosis and patient monitoring.

Metalyse is a powder which is mixed with sterile water for injections before being given into a vein through a drip line.

When you will be given Metalyse

Treatment with Metalyse should be initiated as soon as possible after the start of your symptoms.

If you are given too much Metalyse

An overdose is unlikely because Metalyse is administered under medical supervision.

Symptoms of an overdose may include bleeding.

If you have serious bleeding, your doctor will immediately stop treatment with Metalyse. Your doctor will start appropriate treatment to control the bleeding and, if necessary, replace the lost blood.

5. What should I know while being given Metalyse?

Things you should be careful of

Metalyse increases the risk of bleeding and bruising. After treatment with Metalyse, medical staff will avoid giving you injections or moving you unless absolutely necessary.

Your doctor will probably continue to treat you with other medications after treatment with Metalyse. This is to reduce the risk of more blood clots forming.

You should only receive one injection of Metalyse.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

If you are over 80 years of age you may have an increased chance of getting side effects.

See the information below and, if you need to, ask your doctor if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
Bleeding-related problems: • bleeding or blood clot within the head or brain. Symptoms may include collapse, sleepiness, difficulty in speaking or slurred speech, numbness or weakness of the arms or legs, headache, dizziness, visual disturbance, confusion, loss of memory, agitation, depression, weakness on one side of the body,	**Tell your doctor immediately if you notice any of these serious side effects.**

Serious side effects	What to do
convulsions, fits or seizures, psychosis (a severe mental condition in which the person loses contact with reality and is unable to think and judge clearly), difficulty swallowing • bleeding from the skin, mouth, nose or eyes • bruising • bleeding or bruising where the injection is given • vomiting blood or material that looks like coffee grounds • bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea • blood in the urine • coughing up blood **Signs of an allergic reaction:** • rash, itching or hives on the skin • swelling of the face, lips, mouth, tongue, throat or other parts of the body • shortness of breath • wheezing or difficulty swallowing or breathing **Other side effects:** • low blood pressure • nausea and vomiting • high body temperature (fever)	**Tell your doctor immediately if you notice any of these serious side effects.**

There have also been reports of blockages of blood vessels following treatment with Metalyse. This can lead to organ failure (e.g. kidney failure). These serious effects are rare.

Tell your doctor or nurse if you notice anything that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at https://www.tga.gov.au/safety/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

What Metalyse contains

Active ingredient (main ingredient)	Tenecteplase (25 mg)
Other ingredients (inactive ingredients)	• arginine • phosphoric acid • polysorbate 20

You should not be given this medicine if you are allergic to any of these ingredients.

What Metalyse looks like

Metalyse is the brand name of your medicine.

Metalyse 25 mg comes as a sterile, white to off-white powder in a clear glass vial containing 25 mg tenecteplase. (AUST R 443530)

Metalyse powder must be mixed with sterile water for injections before use. When mixed, the resulting solution is clear, and colourless to pale yellow.

The reconstituted solution contains 5 mg of tenecteplase per mL.

Who distributes Metalyse

Metalyse is supplied in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney NSW

www.boehringer-ingelheim.com.au

This Consumer Medicine Information was prepared in July 2025.

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