

# Metalyse®

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## 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 given during the early stages of a heart attack.

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, have a planned heart procedure, blood vessel problems, high blood**

**pressure, have had a stroke or recent surgery or injury.**

**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 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?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Follow all instructions given to you by your healthcare professionals</li><li>• Avoid moving unnecessarily after receiving Metalyse to prevent bleeding or bruising</li></ul>
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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 75 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; nausea; vomiting; blood in the urine; coughing up blood; low blood pressure; irregular heartbeat; 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<sup>®</sup>

Active ingredient: tenecteplase

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## 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?](#)
- [2. What should I know before I am given Metalyse?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given Metalyse?](#)
- [5. What should I know while being given Metalyse?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 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 during the early stages of a heart attack.**

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 a percutaneous coronary intervention (PCI) planned. PCI is an interventional procedure in which blocked blood vessels in the heart are unblocked. Examples of PCI procedures include balloon angioplasty, atherectomy and stent placement. Receiving Metalyse treatment prior to a planned PCI procedure may increase your risk of having side effects
- are under 18 years of age. The safety and effectiveness in this age group has not been established.

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

- current bleeding or severe bleeding in the past 6 months
- a family history of bleeding disorders

- treatment with an anti-clotting agent (anticoagulant), such as warfarin, unless its effect has had time to wear off
- major surgery, biopsy or significant trauma in the past 2 months
- a stroke due to bleeding in the brain or a stroke of unknown origin at any time
- a stroke caused by a blood clot or a transient ischaemic attack (TIA) in the past 6 months
- severe and uncontrolled high blood pressure (hypertension)
- tumours in which the risk of bleeding is increased
- any blood clotting defect
- current treatment with a thrombolytic agent (medicine used to dissolve blood clots)
- previous or current aneurysms (swelling and weakening of a part of a blood vessel) in your brain or spinal cord, or arteries in other parts of your body
- previous brain or spinal cord surgery
- previous or current tumours in your brain or spinal cord
- recent trauma to your head or skull
- heart and lung resuscitation (CPR) in the past 2 weeks
- structural abnormalities in your arteries or veins
- severe liver disease
- inflammation, infection or swelling of your heart or pancreas
- childbirth, organ biopsy or any invasive medical procedure in the past 10 days

- recent severe bleeding, particularly in your stomach, gut or from your genitals
- problems with your blood, especially if you also have severe liver or kidney disease
- stomach ulcers in the past 3 months.

**Check with your doctor if you have or have had any of the following medical conditions:**

- allergies to any other medicines, foods, preservatives or dyes
- recent major trauma, medical procedure (such as a biopsy or injection) or surgery to any part of your body
- problems with blood supply to the brain
- a previous stroke caused by a blood clot or a transient ischaemic attack (TIA) more than 6 months previously
- recent bleeding from your stomach, gut or genitals
- high blood pressure
- any heart conditions or infections
- severe problems with your pancreas
- severe liver disease
- problems with your blood, especially if you also have severe liver or kidney disease
- diabetes mellitus
- bleeding from inside or around your eyes
- if your body weight is less than 60 kg
- if you are elderly (75 years of age or older).

**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.

## **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.**

**Medicines that may increase the risk of bleeding include:**

- aspirin, heparin, warfarin or any other medicines used to “thin” the blood and prevent blood clots.

**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 is based on your body weight and ranges between 30 mg and 50 mg. The dose is given as a single injection over about 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.

At the same time or soon after treatment with Metalyse, you may also receive other medications such as heparin to help prevent the blood vessel(s) becoming blocked again after treatment.

## **When you will be given Metalyse**

You should be treated with Metalyse as soon as possible after the onset 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 and heparin. 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. Any leftover solution that was prepared to treat you should be thrown away and not injected into anyone else.

## **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 75 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**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Bleeding-related problems:</b></p> <ul style="list-style-type: none"><li>• 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,</li></ul>	<p><b>Tell your doctor immediately if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>confusion, loss of memory, agitation, depression, weakness on one side of the body, 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</p> <ul style="list-style-type: none"> <li>● bleeding from the skin, nose or eyes</li> <li>● bruising</li> <li>● bleeding or bruising where the injection is given</li> <li>● nausea, vomiting or vomiting blood or material that looks like coffee grounds</li> <li>● bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea</li> <li>● blood in the urine</li> <li>● coughing up blood</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Signs of heart problems:</b></p> <ul style="list-style-type: none"> <li>● low blood pressure</li> <li>● irregular heartbeat</li> </ul> <p><b>Signs of an allergic reaction:</b></p> <ul style="list-style-type: none"> <li>● rash, itching or hives on the skin</li> <li>● swelling of the face, lips, mouth, tongue, throat or other parts of the body</li> <li>● shortness of breath</li> <li>● wheezing or difficulty swallowing or breathing</li> <li>● low blood pressure</li> </ul> <p><b>Other side effects:</b></p> <ul style="list-style-type: none"> <li>● nausea and vomiting</li> <li>● high body temperature (fever)</li> </ul>	

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 [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

## 7. Product details

### What Metalyse contains

<b>Active ingredient (main ingredient)</b>	Tenecteplase (40 mg or 50 mg)
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• arginine</li><li>• phosphoric acid</li><li>• polysorbate 20</li><li>• sterilised water for injections</li></ul>

**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.

It comes as a sterile, white to off-white powder in a clear glass vial. Metalyse powder must be mixed with sterile water for injections before use. When mixed, the resulting solution is clear, and colourless to pale yellow.

Metalyse is sold as a pack containing one vial of powder and one pre-filled syringe of sterile water for injections.

Metalyse is available in two strengths:

- Metalyse 40 mg: One vial of powder with 40 mg tenecteplase and one pre-filled syringe containing 8 mL of sterilised Water for Injections (AUST R 75012)
- Metalyse 50 mg: One vial of powder with 50 mg tenecteplase and one pre-filled syringe containing 10 mL of sterilised Water for Injections (AUST R 75013)

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](http://www.boehringer-ingelheim.com.au)

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