

## 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, liver disease, a stomach ulcer or disease of stomach/intestine, have had a stroke, have had recent major injury/trauma or a medical procedure (such as surgery or biopsy).**

**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 healthcare professional as soon as possible after the start of your symptoms.

More instructions 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

## 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

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

- a bleeding disorder at present or within the past 6 months, or a known tendency to bleed
- treatment with medicines to thin your blood, such as warfarin and when your blood tests show that your blood is still too thin
- 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
- major surgery, biopsy or significant trauma in the past 2 months (including any trauma associated with heart attack)
- recent trauma to your head or skull
- aneurysms (swelling and weakening of a part of a blood vessel) in your arteries

- structural abnormalities in your arteries or veins
- tumours in which the risk of bleeding is increased
- a stroke due to bleeding in the brain or a stroke of unknown origin at any time
- severe and uncontrolled high blood pressure (hypertension)
- severe liver disease or liver problems
- swelling of the lining that surrounds the heart
- inflammation of the lining of the heart caused by bacteria
- inflammation of the pancreas
- active stomach ulcer or disease of the stomach/intestine.

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

- allergies to any other medicines, foods, preservatives or dyes
- any blood clotting defect
- a previous stroke or a transient ischaemic attack (TIA)
- a family history of bleeding disorders
- recent bleeding, particularly in your stomach, gut or from your genitals in the past 10 days
- any recent major trauma, medical procedure (such as a biopsy or injection) or surgery to any part of your body
- high blood pressure
- any heart conditions
- percutaneous coronary intervention (PCI) is 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
- have received heart and lung resuscitation (CPR)
- If you are taking anticoagulants (medicines used to “thin” the blood) e.g. warfarin, dabigatran, rivaroxaban or apixaban, unless tests have confirmed that the effect of the medicine has had time to wear off
- weigh less than 50 kg
- are 75 years of age or older.

**Your doctor will carefully weigh the risks and benefits before giving you Metalyse if any of the above conditions apply to you.**

**If you are uncertain as to whether you have, or have had, any of these conditions you should raise these concerns with your doctor.**

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

**Check with 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 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.

If you want more information, ask your doctor.

### 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 must be 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

Serious side effects	What to do
<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, 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</li><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>	<p><b>Tell your doctor immediately if you notice any of these serious side effects.</b></p>

<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, 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</li> </ul>	<p><b>Tell your doctor immediately if you notice any of these serious side effects.</b></p>
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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 online at <https://pophealth.my.site.com/carmreportnz/s/>. 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 clear glass vials. Metalyse powder must be mixed with sterile water for injections before use. When mixed, the resulting solution is 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
- Metalyse 50 mg: One vial of powder with 50 mg tenecteplase and one pre-filled syringe containing 10 mL of sterilised Water for Injections

\*Not distributed in New Zealand

### Who distributes Metalyse

Metalyse is supplied in New Zealand by:

Boehringer Ingelheim (N.Z.) Limited

PO Box 76-216

Manukau City

Auckland

Telephone 0800 802 461

This Consumer Medicine Information was prepared in January 2026.

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