

New Zealand Consumer Medicine Information

METALYSE[®]

Tenecteplase

What is in this leaflet

This leaflet answers some common questions about METALYSE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using METALYSE against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp and may contain important information about the medicine and its use of which you should be aware.

Keep this information with the medicine. You may need to read it again.

What METALYSE is used for

METALYSE is used during the early stages of a heart attack. METALYSE works by dissolving clots in the blood vessels. These clots cause disease by interfering with normal blood flow.

Ask your doctor if you have any questions about why METALYSE has been prescribed for you. Your doctor may have prescribed METALYSE for another reason.

Before being given METALYSE

When you must not be given it

You must not be given METALYSE if you have or have had:

- an allergy to any medicine containing tenecteplase; gentamicin (a trace residue from the manufacturing process) or to any of the ingredients listed at the end of this leaflet
- current bleeding or severe bleeding in the past 6 months
- current treatment with an anticlotting 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
- 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
- active stomach ulcers.

METALYSE must not be given if 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 planned PCI procedure may increase your risk for side effects.

If you are not sure whether you should be given METALYSE, talk to your doctor.

Before you are given it

It is important that your doctor knows your medical history before administering METALYSE.

Tell your doctor if you have, or have had any of the following medical conditions:

- 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
- severe problems with your pancreas
- problems with blood supply to the brain
- current treatment with drugs that affect the ability of the blood to clot (these include agents known as platelet aggregation inhibitors)
- if you are pregnant or breast feeding
- if your body weight is less than 60 kg
- if you are elderly (older than 75 years of age).

If you have not told your doctor about any of the above, tell them before you are given METALYSE.

Taking other medicines

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

Some medicines may interfere with METALYSE. These include anticlotting agents (anticoagulants), such as warfarin, low molecular weight heparin or any other medicines which affect the ability of the blood to clot.

These medicines may be affected by METALYSE, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor has more information on medicines to be careful with or avoid while being given this medicine.

How METALYSE is given

How much is 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 might prescribe a different dose or duration of treatment to that described here. If you want more information, ask your doctor.

How it is given

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 to help prevent the blood vessel(s) becoming blocked again after treatment. METALYSE should only be used under the supervision of a doctor and in a setting where appropriate equipment is readily available for diagnosis and patient monitoring.

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.

When to be given it

Treatment with METALYSE should begin as soon as possible after the onset of symptoms.

While you are being given METALYSE

Things you must do

Tell any other doctors, dentists, and pharmacists who treat you that you have been given this medicine.

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.

In case of overdose

If you are given too much (overdose)

As METALYSE is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

Symptoms of an overdose may include bleeding.

In the case of 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.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given METALYSE.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or nurse to answer any questions you may have.

The most common side effect is bleeding. Bleeding may be obvious if it is from the skin, nose or eyes. A more serious situation is when bleeding occurs inside the body (internally), for example, bruising and stroke (bleeding in the brain).

Other symptoms such as drowsiness, difficulty speaking, inability to move parts of your body and convulsion may also occur if you experience bleeding in the brain.

Internal bleeding can occur at any site or body cavity and may result in life-threatening situations, permanent disability or death.

Other very common side effects reported include irregular heartbeats and low blood pressure. Common side effects reported include nausea, vomiting and fever. These events commonly occur after a heart attack and may or may not be caused by METALYSE.

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.

There have also been reports of serious or life-threatening allergic reactions, which can cause low blood pressure and difficulty breathing.

Other side effects not listed above may also occur in some people. Tell your doctor or nurse if you notice anything unusual, during or after treatment with METALYSE.

After using METALYSE

Storage

METALYSE will be stored in the pharmacy or ward below 30°C and protected from light.

After mixing with sterile water for injections, METALYSE can be kept for up to 24 hours in a refrigerator (2-8°C) and 8 hours at 30°C.

Disposal

Each vial of METALYSE can only be used once and unused contents of opened vials must be discarded.

METALYSE must not be given after the expiry date printed on the pack or vial or if the packaging is torn or shows signs of tampering.

Product Description

What it looks like

METALYSE is the brand name of the 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.

Ingredients

Active ingredient:

Each METALYSE 40 mg* powder for injection vial contains 40 mg of tenecteplase.

Each METALYSE 50 mg powder for injection vial contains 50 mg of tenecteplase.

*Not distributed in New Zealand.

Inactive ingredients:

The powder for injection also contains:

- L-arginine
- phosphoric acid, and
- polysorbate 20.

The pre-filled syringes contain 8 or 10 mL of sterile water for injections.

Sponsor details

METALYSE is supplied in New Zealand by:

Boehringer Ingelheim (N.Z.) Limited
PO Box 76-216
Manukau City
Auckland

Telephone 0800 802 461

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This leaflet was revised on 3 March 2016.

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