

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 available information. It does not take the place of talking to your doctor or pharmacist. Consider keeping this information even after your treatment is finished. You may want to read it again later.

To find out more about METALYSE

You should ask your doctor or pharmacist if you have any questions about your medicine or if you have any concerns about being treated with METALYSE.

What METALYSE is used for

METALYSE is intended to be 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. If you want more information about what METALYSE is used for, ask your doctor.

Before being treated with METALYSE

When METALYSE should not be used

You should not be given METALYSE if you are allergic to it or to any of the ingredients. These ingredients are listed in full at the end of this leaflet. If you are uncertain as to whether you have such an allergy you should raise this concern with your doctor.

You should not be given METALYSE 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.

Because of the risk of bleeding, METALYSE should not be used if you have, or have had:

- current bleeding or severe bleeding in the past 6 months
- a family history of bleeding disorders
- current treatment with an anticlotting agent (anticoagulant), such as warfarin
- 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.

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

METALYSE must not be used after the EXPIRY DATE on the carton or vial.

Before treatment with METALYSE

It is important that your doctor knows your medical history before administering METALYSE. Before being treated with METALYSE, your doctor should know if you have, or have had, any of the following conditions:

- any recent major trauma, medical procedure (such as a biopsy or injection) or surgery to any part of your body
- 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

- current treatment with an anticlotting agent (anticoagulant), such as warfarin
- current treatment with a thrombolytic agent (medicine used to dissolve blood clots)
- if you are pregnant
- if your body weight is less than 60 kg
- if you are elderly (older than 75 years of age).

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

Before METALYSE is administered your doctor should know if you are taking any other medicines, and in particular if you have ever taken:

- warfarin or any other drug which affects the ability of the blood to clot (these include agents known as anticoagulants and platelet aggregation inhibitors).

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.

Pregnancy

The risks of treatment with METALYSE during pregnancy are unknown. You must tell your doctor if you are, or may be, pregnant.

Breastfeeding

It is not known whether METALYSE enters the breast milk. Special care is recommended if you are breastfeeding and you should ask for your doctor's advice in this situation.

Children

There is not enough information available to recommend the use of METALYSE in children.

Elderly patients

The risks of treatment with METALYSE may be increased in elderly patients (patients older than 75 years of age).

Treatment with METALYSE

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

How METALYSE is used

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 left over solution that was prepared to treat you, should be thrown away and not injected into anyone else.

Recommended dose

The recommended dose is based on the patient's 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.

Overdose

Overdose is unlikely because METALYSE is administered under medical supervision. If too much METALYSE is administered, the most likely effect is 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.

After treatment with METALYSE

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.

Side effects

You should be aware that all prescription medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing. Your doctor has weighed the risks of using METALYSE against the benefits they expect it will have for you. Ask for the advice of your doctor or other medical staff if you have any concerns about the effects of being treated with this medicine.

The most common side effect is bleeding. This may have an effect on your blood readings. 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 side effects reported include nausea, vomiting, low blood pressure, irregular heart beat 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 (eg. 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.

Tell your doctor as soon as possible if you experience any side effects during or after treatment with METALYSE, so that these may be properly treated. In addition, unexpected effects, not listed above, can occur with any medicine. You should tell your doctor if you notice anything unusual, during or after treatment with METALYSE.

Storing METALYSE

METALYSE powder must be stored 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). After this, it must be thrown away.

Product Description

What the product looks like

METALYSE is the brand name of the medicine prescribed for you by your doctor. 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

Vials of METALYSE powder containing 40 or 50 mg of tenecteplase. The powder also contains:

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

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

Manufacturer

METALYSE is made in Germany and supplied in New Zealand by:

Boehringer Ingelheim (N.Z.) Limited
Unit 9, 42 Ormiston Road, East Tamaki, Auckland
Telephone (09) 274-8664 or 0800 802 461

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