

Metalyse® 10 000 units (50 mg) powder and solvent for solution for injection



tenecteplase

Read all of this leaflet carefully before you receive this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Metalyse is and what it is used for
2. What you need to know before you receive Metalyse
3. How is Metalyse administered
4. Possible side effects
5. How to store Metalyse
6. Contents of the pack and other information

1. What Metalyse is and what it is used for

Metalyse is a powder and solvent for solution for injection.

Metalyse belongs to a group of medicines called thrombolytic agents. These medicines help to dissolve blood clots. Tenecteplase is a recombinant fibrin-specific plasminogen activator.

Metalyse is used to treat myocardial infarctions (heart attacks) within 6 hours after the onset of symptoms and helps to dissolve the blood clots that have formed in the blood vessels of the heart. This helps to prevent the damage caused by heart attacks and has been shown to save lives.

2. What you need to know before you receive Metalyse

Metalyse will not be prescribed and given by your doctor

- if you have previously had a sudden life-threatening allergic reaction (severe hypersensitivity) to tenecteplase, to any of the other ingredients of this medicine (listed in section 6) or to gentamicin (a trace residue from the manufacturing process). If treatment with Metalyse is nevertheless considered to be necessary, facilities for reanimation should be immediately available in case of need;
- if you have, or have recently had, an illness that increases your risk of bleeding (haemorrhage), including:
 - a bleeding disorder or tendency to bleed (haemorrhage)
 - stroke (cerebrovascular event)
 - very high, uncontrolled blood pressure
 - a head injury
 - severe liver disease
 - a stomach ulcer (peptic ulcer)
 - varicose veins in the gullet (oesophageal varices)
 - abnormality of the blood vessels (e.g. an aneurysm)
 - certain tumours
 - inflammation of the lining around the heart (pericarditis); inflammation or infection of the heart valves (endocarditis)
 - dementia;
- if you are taking tablets/capsules used to “thin” the blood, such as coumarin derivatives like warfarin (anti-coagulants);
- if you have an inflamed pancreas (pancreatitis);
- if you have recently had major surgery including surgery to your brain or spine;
- if you have been given cardiopulmonary resuscitation (chest compressions) for more than 2 minutes duration, in the last two weeks.

Warnings and precautions

Your doctor will take special care with Metalyse

- if you have had any allergic reaction other than a sudden life-threatening allergic reaction (severe hypersensitive) to tenecteplase, to any of the other ingredients of this medicine (listed in section 6) or to gentamicin (a trace residue from the manufacturing process);
- if you have high blood pressure;
- if you have problems with circulation of blood in the brain (cerebrovascular disease);
- if you have had gastrointestinal (gut) or genitourinary bleeding within the last ten days (this may cause blood in stools or urine);
- if you have a heart valve abnormality (e.g. mitral stenosis) with an abnormal heart rhythm (e.g. atrial fibrillation);
- if you have had an intramuscular injection in the last two days;
- if you are aged over 75 years;
- if you weigh less than 60 kg;
- if you have ever received Metalyse before.

Children and adolescents

The use of Metalyse in children and adolescents up to the age of 18 years is not recommended.

Other medicines and Metalyse

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.

3. How is Metalyse administered

The doctor calculates your dose of Metalyse according to your bodyweight, based on the following scheme:

Bodyweight (kg)	Metalyse (U)
less than 60	6 000
60 to 70	7 000
70 to 80	8 000
80 to 90	9 000
above 90	10 000

Your doctor will give you the medicinal product to prevent blood clotting in addition to Metalyse, as soon as possible after your chest pain starts.

Metalyse is given by a single injection into a vein by a doctor who is experienced in the use of this type of medicinal product.

Your doctor will give Metalyse as soon as possible after your chest pain starts as a single dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects described below have been experienced by people given Metalyse:

Very common (may affect more than 1 in 10 people):

- Bleeding

Common (may affect up to 1 in 10 people):

- Bleeding at the injection or puncture site
- Nosebleeds
- Genitourinary bleeding (you may notice blood in your urine)
- Bruising
- Gastro-intestinal bleeding (e.g. bleeding from the stomach or bowel)

Uncommon (may affect up to 1 in 100 people):

- Irregular heart beat (reperfusion arrhythmias), sometimes leading to cardiac arrest. Cardiac (heart) arrest can be life threatening.
- Internal bleeding in the abdomen (retroperitoneal bleeding)
- Bleeding in the brain (cerebral haemorrhage). Death or permanent disability may occur following bleeding in the brain or other serious bleeding events
- Bleeding in the eyes (eye haemorrhage)

Rare (may affect up to 1 in 1 000 people):

- Low blood pressure (hypotension)
- Bleeding in the lungs (pulmonary haemorrhage)
- Hypersensitivity (anaphylactoid reactions) e.g. rash, hives (urticaria), difficulty breathing (bronchospasm)
- Bleeding into the area surrounding the heart (haemopericardium)
- Blood clot in the lung (pulmonary embolism) and in the vessels of other organ systems (thrombotic embolisation)

Not known (frequency cannot be estimated from the available data):

- Fat embolism (clots consisting of fat)
- Nausea
- Vomiting
- Body temperature increased (fever)
- Blood transfusions as consequence of bleedings

As with other thrombolytic agents, the following events have been reported as sequelae of myocardial infarction and/or thrombolytic administration:

Very common (may affect more than 1 in 10 people):

- Low blood pressure (hypotension)
- Irregular heart beat
- Chest pain (angina pectoris)

Common (may affect up to 1 in 10 people):

- Further chest pain/angina (recurrent ischaemia)
- Heart attack
- Heart failure
- Shock due to heart failure
- Inflammation of the lining around the heart
- Fluid in the lungs (pulmonary oedema)

Uncommon (may affect up to 1 in 100 people):

- Heart arrest
- Problem with the heart valve or heart lining (mitral valve incompetence, pericardial effusion)
- Blood clot in the veins (venous thrombosis)
- Fluid between the heart lining and the heart (cardiac tamponade)
- Rupture of the heart muscle (myocardial rupture)

Rare (may affect up to 1 in 1 000 people):

- Blood clot in the lung (pulmonary embolism)

These cardiovascular events can be life-threatening and may lead to death.

In case of bleeding in the brain events related to the nervous system have been reported e.g. drowsiness (somnolence), speech disorders, palsy of parts of the body (hemiparesis) and fits (convulsions).

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Metalyse

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP.

Do not store above 30 °C.

Keep the container in the outer carton in order to protect from light.

Once Metalyse has been reconstituted it may be stored for 24 hours at 2-8 °C and 8 hours at 30 °C. However, for microbiological reasons your doctor will normally use the reconstituted solution for injection immediately.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Metalyse contains

- The active substance is tenecteplase.
- Each vial contains 10 000 units (50 mg) of tenecteplase. Each pre-filled syringe contains 10 mL of solvent. When reconstituted with 10 mL solvent each mL contains 1 000 U tenecteplase.
- The other ingredients are arginine, concentrated phosphoric acid and polysorbate 20.
- The solvent is water for injections.
- Gentamicin is contained as trace residue from the manufacturing process

What Metalyse looks like and contents of the pack

The carton contains:

- one vial with a lyophilised powder with 50 mg tenecteplase, one ready for use pre-filled syringe with 10 mL solvent and one vial adapter.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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