Package leaflet: Information for the user

Metalyse®
5 000 units (25 mg)
powder 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

Metalyse is a powder 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 in adults to treat stroke caused by a blood clot in an artery of the brain (acute ischaemic stroke) when it has been less than 4.5 hours since you were last seen without the symptoms of your current stroke.

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);
  - very high, uncontrolled blood pressure;
  - a head injury;
  - inflammation of the lining around the heart (pericarditis); inflammation or infection of the heart valves (endocarditis);
  - severe liver disease;
  - varicose veins in the gullet (oesophageal varices);
  - a stomach ulcer (peptic ulcer);
  - abnormality of the blood vessels (e.g. an aneurysm);
  - certain tumours;
  - bleeding within the brain or skull;
- if you are taking tablets/capsules used to "thin" the blood (anti-coagulants), unless appropriate test confirmed no clinically relevant activity of such medicine;
- if you have a very severe stroke;
- if your stroke is causing only minor symptoms;
- if the symptoms are rapidly improving before receiving Metalyse;
- if the symptoms of your stroke began more than 4.5 hours ago or if it may be possible that the symptoms began more than 4.5 hours ago, because you do not know when they began;
- if you had cramps (convulsions) when your stroke started;
- if your thromboplastin time (a blood test to see how well your blood clots) is abnormal. This test can be abnormal if you have received heparin (a medicine used to "thin" the blood) within the previous 48 hours;
- if you are diabetic and have ever had a stroke before;
- if you have had a stroke within the last three months;
- if the number of blood platelets (thrombocytes) in your blood is very low;
- if you have a very high blood pressure (above 185/110) which can only be reduced by injection of medicines;
- if the amount of sugar (glucose) in your blood is very low (under 50 mg/dL) or very high (over 400 mg/dL);
- if you have recently had major surgery including surgery to your brain or spine;
- if you have recently had a biopsy (a procedure for obtaining a tissue specimen);
- if you have been given cardiopulmonary resuscitation (chest compressions) for more than 2 minutes duration, in the last two weeks;
- if you have an inflamed pancreas (pancreatitis).

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 or have recently had any other conditions that increase your risk of bleeding, such as:
  - an intramuscular injection
  - a small injury such as a puncture of major vessels or external heart massage
  - if you weigh less than 60 kg;
- if you are aged over 80 years, you may have a poorer outcome regardless of treatment with Metalyse. However, in general the benefit-risk of Metalyse in patients over 80 years is positive and age alone is not a barrier to treatment with Metalyse;
- 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. It is particularly important that you tell your doctor if you are taking or have recently taken:
- any medicines which are used to "thin" the blood
- certain medicines used to treat high blood pressure (ACE inhibitors).

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)	less than 60	60 to 70	70 to 80	80 to 90	above 90
Metalyse (U)	3 000	3 500	4 000	4 500	5 000

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 stroke 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
- Bleeding in the brain (cerebral haemorrhage). Death or permanent disability may occur following bleeding in the brain or other serious bleeding events

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):
- Internal bleeding in the abdomen (retroperitoneal bleeding)
- 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

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 5 000 units (25 mg) of tenecteplase. When reconstituted with 5 mL water for injection each mL contains 1 000 U tenecteplase.
- The other ingredients are arginine, concentrated phosphoric acid and polysorbate 20.
- 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 25 mg tenecteplase,

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Boehringer Ingelheim International GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

Manufacturer

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Birkendorfer Strasse 65
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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