PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

Metalyse® 8 000 U & 10 000 U

Boehringer Ingelheim

Powder for solution for injection.
Tenecteplase
Sugar free

Metalyse® solvent

Solvent for injection
Water for injection
Sugar free

Read all of this leaflet carefully before you are given METALYSE.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.

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 to receive METALYSE
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 belongs to a group of medicines called thrombolytic agents. These medicines help to dissolve blood clots.

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.

2. What you need to know before you receive METALYSE

METALYSE treatment should be carried out by a doctor who is experienced in the use of this type of medicine.

Your doctor will not use METALYSE if you have, or have recently had any illness, medicine or medical procedure which is associated with a high risk of haemorrhage (bleeding).

METALYSE should not be administered to you

- if you are hypersensitive (allergic) to the active ingredient (tenecteplase), gentamicin (a trace residue from the manufacturing process) or any of the other ingredients of METALYSE listed in section 6.
- if you have, or have recently had, a situation 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)
  - if you are taking tablets/capsules used to "thin" the blood, such as warfarin or coumarin (anticoagulants)
  - 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
  - if you gave birth within the previous 3 days
- if you are pregnant or breastfeeding (see below)
- if you had previous treatment with tenecteplase
- if you are older than 80 years or younger than 18 years of age.

Warnings and precautions

Tell your doctor or healthcare provider before being given the injection:

- 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.

Children and adolescents

The use of METALYSE in children and adolescents up to 18 years is not recommended.

Other medicines and METALYSE
Always tell your healthcare provider if you are taking any other medicines. (This includes all complementary or traditional medicines.)

Medicines that affect coagulation (clotting) or those that alter platelet function may increase the risk of bleeding prior to, during or after METALYSE therapy.

Pregnancy and breastfeeding
Safety in using METATYSE in pregnant and breastfeeding women has not been established.

METALYSE may contain gentamicin
METALYSE may contain gentamicin as a trace residue from the manufacturing process.

3. How to receive METALYSE
You will not be expected to give yourself METALYSE. It will be given to you by a person who is qualified to do so.

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)	6 000	7 000	8 000	9 000	10 000

Your doctor will give you medication 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 medicine.

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

Repetition is not recommended.

If you are given more METALYSE than you should have received
Since a healthcare provider will administer METALYSE, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects
METALYSE can cause side effects.
Not all side effects reported for METALYSE are included in this leaflet. Should your general health worsen, or if you experience untoward effects after receiving METALYSE, please consult your healthcare provider for advice.

Tell your doctor if you notice any of the following:

Frequent side effects

- low blood pressure (hypotension)
- irregular heart beat
- chest pain (angina pectoris)
- bleeding where the injection is given
- nosebleeds
- further heart attack or chest pain (recurrent ischaemia, reinfarction)
- heart failure
- shock due to heart failure
- inflammation of the lining around the heart (pericarditis)
- fluid in the lungs (pulmonary oedema)
- genitourinary bleeding (you may notice blood in your urine)
- bruising
- gastrointestinal bleeding (bleeding from the stomach or bowel)

Less frequent side effects

- cardiac arrest
- problem with the heart valve or heart lining (mitral insufficiency, pericardial effusion)
- blood clot in the vein (venous thrombosis)
- blood clot in the blood vessel (thrombotic embolisation)
- fluid between heart lining and the heart (cardiac tamponade)
- rupture in heart muscle
- 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 lungs (pulmonary haemorrhage)
- hypersensitivity (anaphylactoid reactions) e.g. rash, hives (urticaria), swelling of the throat
- bleeding into the area surrounding the heart (pericardial haemorrhage)
- blood clot in the lung (pulmonary embolism)
- bleeding in the eyes (eye haemorrhage).

Side effects where frequency is not known

- clot consisting of fat
- nausea
- vomiting
- fever
- bleedings requiring blood transfusion

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

Frequent side effects

- Low blood pressure (hypotension)
- Irregular heart beat
- Chest pain (angina pectoris), which can be recurrent

- Heart attack
- Heart failure
- Shock due to heart failure
- Inflammation of the lining around the heart
- Fluid in the lungs (pulmonary oedema)

Less frequent side effects
- 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)
- 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 (inability to move one side of the body) and fits (convulsions).

Tell your doctor immediately if you think you are experiencing any of these side effects.

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications https://www.sahpra.org.za. By reporting side effects, you can help provide more information on the safety of METALYSE.

5. How to store METALYSE
Store all medicines out of reach of children.
Both the vials and the solvent should be stored at or below 30 °C.
Keep the glass vial containing METALYSE powder 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 for 8 hours at 30 °C. However, for microbiological reasons your doctor will normally use the reconstituted solution for injection immediately.

Do not use METALYSE after the expiry date which is stated on the label/carton.

6. Contents of the pack and other information

What METALYSE contains

Each METALYSE 8 000 U vial contains 40 mg tenecteplase as the active ingredient.
The prefilled syringe contains 8 mL water for injection.

Each METALYSE 10 000 U vial contains 50 mg tenecteplase as the active ingredient.
The prefilled syringe contains 10 mL water for injection.

Before use, the solvent (water for injection) is added to the powder to form a solution that is given by injection. The reconstituted solution contains 1 000 units (5 mg) tenecteplase per mL.

Each vial also contains the following inactive ingredients:
L-arginine, phosphoric acid and polysorbate 20.
Trace residue: gentamicin from the manufacturing process.

What METALYSE looks like and contents of the pack

The folding box contains one clear glass vial with grey rubber stopper containing a white to pale yellow cake of lyophilised powder, one 10 mL ready for use transparent plastic syringe with a grey stopper containing clear colourless liquid (solvent) and one vial adapter.

Holder of Certificate of Registration

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