APPROVED PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Metalyse® 8000 U & 10 000 U

Boehringer Ingelheim

Powder for solution for injection.
Tenecteplase

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 or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

METALYSE Solvent
Solvent for injection
Water for injection

1. WHAT METALYSE CONTAINS

Each METALYSE 8000 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.

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

2. WHAT METALYSE 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.

3. BEFORE RECEIVING YOUR 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).

You should not receive METALYSE in the following conditions:

- 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
- 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)
- 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
- pregnancy and breastfeeding (see below)
- previous treatment with tenecteplase
- if you are older than 80 years or younger than 18 years of age.

Special care should be taken with METALYSE

- 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.

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

Using other medicines with METALYSE
If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of METALYSE with these medicines may cause undesirable interactions. Please inform your doctor or other healthcare professional before you are given METALYSE.

4. HOW METALYSE IS GIVEN
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.

5. POSSIBLE SIDE EFFECTS
METALYSE can cause side effects.

The following side effects are frequent with METALYSE:
- low blood pressure (hypotension)
- irregular heart beat
- chest pain (angina pectoris)
- bleeding where the injection is given
- nausea
- vomiting
- fever
- 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
- gastro-intestinal bleeding (bleeding from the stomach or bowel)
- bleedings requiring blood transfusion.

The following side effects are less frequent, but have been reported following treatment with METALYSE:

- 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)
- clot consisting of fat
- bleeding in the eyes (eye haemorrhage).

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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Not all side effects reported for METALYSE are included in this leaflet. Should your general health worsen, please consult your doctor.

6. STORING AND DISPOSING OF METALYSE

Keep out of the reach and sight 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 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.

7. PRESENTATION OF METALYSE
The folding box contains one vial with a lyophilised powder, one ready for use syringe with a solvent and one vial adapter.

8. IDENTIFICATION OF METALYSE
Clear glass vial with grey rubber stopper containing a white to pale yellow cake of powder and one 10 mL transparent plastic syringe with grey stopper containing clear colourless liquid (solvent).
Reconstitution results in a colourless to slightly yellow, clear solution.

9. REGISTRATION NUMBERS
METALYSE 8 000 U: 34/31/0409
METALYSE 10 000 U: 34/31/0410
METALYSE solvent: 34/32.4/0411

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Ingelheim Pharmaceuticals (Pty) Ltd
Suite 1, Building 4, 2nd Floor
Waterfall Corporate Campus
74 Waterfall Drive
Midrand
South Africa
Tel no.: +27(0)11 348 2400

11. DATE OF PUBLICATION
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