Boehringer Ingelheim

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ACTILYSE® 50 mg



powder for solution for injection/infusion

Alteplase

Sugar free

ACTILYSE® SOLVENT

solvent for injection

Water for injection

Sugar free

Read all of this leaflet carefully before you are given ACTILYSE

- 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 ACTILYSE is and what it is used for

2. What you need to know before you receive ACTILYSE
3. How to receive ACTILYSE
4. Possible side effects
5. How to store ACTILYSE
6. Contents of the pack and other information

1. What ACTILYSE is and what it is used for

ACTILYSE belongs to a group of medicines called fibrinolytic agents which help to break down blood clots formed in the blood vessels of the heart, lungs and brain.

ACTILYSE is used to treat a number of conditions caused by blood clots forming within blood vessels, including:

- heart attacks caused by blood clots in the arteries of the heart (myocardial infarction)
- blood clots in the arteries of the lungs (pulmonary embolism)
- stroke caused by a blood clot in an artery of the brain (acute ischaemic stroke).

2. What you need to know before you receive ACTILYSE

ACTILYSE should only be used by a doctor who is experienced in the use of this type of medicine.

ACTILYSE should not be administered to you if you have any of the following conditions:

- if you are allergic (hypersensitive) to alteplase (the active ingredient) or to any of the excipients of ACTILYSE (listed in section 6)

- if you have, or have recently had any illness, medicine or medical procedure which is associated with a high risk of haemorrhage (bleeding)
- bleeding tendency or recent severe bleeding (within the last 6 months)
- if you are taking oral anticoagulants (medicines used to “thin” the blood) e.g. warfarin, dabigatran, rivaroxaban or apixaban, unless appropriate tests confirmed that the effect of the medicine is not too high
- uncontrolled high blood pressure
- history of spinal damage/surgery, brain tumour, aneurysm (balloon-like bulge in an artery or a blood clot in the brain) within the past 3 months
- major surgery, major fracture, major biopsy (a procedure for obtaining a tissue specimen) or significant injury in the past 6 weeks
- bacterial endocarditis (infection within the heart) or pericarditis (inflammation of the lining of the heart or the membrane surrounding the heart)
- severe liver disease (such as cirrhosis) or acute pancreatitis (inflammation of the pancreas)
- if you have had a baby within the past 10 days
- recent puncture of a large blood vessel
- history or evidence of brain haemorrhage (bleeding)
- active oesophageal, gastric or duodenal ulcers
- known blood vessel malformations
- tumour with increased bleeding risk
- if you have had a stroke with brain bleeding or a stroke where the cause is unknown.

In addition, for the treatment of a blood clot in the brain (acute ischaemic stroke), you should not be given ACTILYSE in the following conditions:

- if your stroke symptoms rapidly improve or are mild in nature
- if your stroke is severe
- if you have had a serious head injury within 3 months
- if you have had the medicine heparin injected within the past 48 hours and you have blood clotting problems
- if you have abnormal blood clotting
- if you are under 16 years of age. For adolescents of 16 years of age or older see section "Warnings and precautions" below.

Warnings and precautions

Take special care with ACTILYSE:

There is no experience with the re-administration of ACTILYSE.

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

- if you have recently had a biopsy (a procedure for obtaining a tissue specimen), intramuscular injection or puncture of a major blood vessel
- if you had cardiopulmonary resuscitation or cardiac massage which lasted longer than 2 minutes
- if you have previously had a stroke or transient ischaemic attack (TIA)

In addition, when being treated for a blood clot in the heart or lungs, tell your doctor or healthcare provider:

- if your systolic blood pressure is > 160 mmHg

- if you are 75 years or older
- if you weigh less than 50 kg

In addition, when being treated for a blood clot in the brain, tell your doctor or healthcare provider:

- if you had a fit (convulsions) at the start of the stroke
- if you are older than 80 years of age

  The risk of bleeding on the brain is increased in elderly patients.

  If you are over 80 years of age, you may have a poorer outcome regardless of treatment with ACTILYSE. However, in general the benefit-risk of ACTILYSE in patients over 80 years is positive and age alone is not a barrier to treatment with ACTILYSE. Your doctor will carefully weigh up the benefit versus the potential risks of the treatment.
- if you have very high blood pressure (above 185/110 mmHg) which can only be reduced by injection of medicines
- if the amount of sugar (glucose) in your blood is very low (under 2,8 mmol/L) or very high (over 22,2 mmol/L)
- if you are diabetic and have ever had a stroke before

Children and adolescents

There is only limited experience with the use of ACTILYSE in children. If you are an adolescent of 16 years of age or older the benefit will be weighed carefully against the risks on an individual basis for the treatment of a blood clot on the brain (acute ischaemic stroke).

Other medicines and ACTILYSE

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

There is a possibility that medicines called ACE inhibitors (used to treat high blood pressure and some other heart conditions) may increase the risk of suffering an allergic reaction with ACTILYSE.

Medicines that affect coagulation (clotting) e.g. warfarin, dabigatran, rivaroxaban or apixaban, or platelet function e.g. aspirin (acetylsalicylic acid), may increase the risk of bleeding before, during or after ACTILYSE therapy.

Pregnancy and breastfeeding

Safety in using ACTILYSE in pregnant and breastfeeding women has not been established. If you are pregnant or breastfeeding please inform your doctor, who will only give you ACTILYSE if the benefit to you outweighs the potential risks to you and your baby.

ACTILYSE contains polysorbate 80

This medicine contains 5,0 mg of polysorbate 80 in each 50 mg vial. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How to receive ACTILYSE

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

ACTILYSE should be given as soon as possible after the onset of symptoms (e.g. pain).

A total dose of more than 100 mg should not be given.

There are three different conditions for which ACTILYSE can be given:

A) In patients with a blood clot in the heart (myocardial infarction) in whom treatment can be started within 6 hours after symptom onset, ACTILYSE should be given intravenously according to the following dosage regimen:

- 15 mg as an initial dose, followed by an infusion of 50 mg over 30 minutes followed by a further infusion of 35 mg over 60 minutes up to a maximum dose of 100 mg.

In patients with a body weight below 65 kg the dose should be adjusted to:

- 15 mg as an initial dose and 0,75 mg/kg body weight over 30 minutes (maximum 50 mg), followed by an infusion of 0,5 mg/kg over 60 minutes (maximum 35 mg). The total dose should not exceed 1,5 mg/kg.

You will receive additional medication following treatment with ACTILYSE.

B) In patients with a blood clot in the lungs (pulmonary embolism), a total dose of 100 mg should be given intravenously. An initial dose of 10 mg is given over 1 to 2 minutes, followed by an infusion of 90 mg over 2 hours.

For patients weighing less than 65 kg a total dose should not exceed 1,5 mg/kg.

Following treatment with ACTILYSE, heparin therapy can be started or resumed.

C) In patients with a blood clot in the brain (acute ischaemic stroke) ACTILYSE must be given within 4,5 hours from when you were last feeling well. Your doctor will calculate your dose of ACTILYSE using your body weight. You should be given 0,9 mg/kg to a maximum dose of 90 mg. ACTILYSE is given as an intravenous infusion over 60 minutes with 10 % of the total dose given as an initial injection.

You should not take any aspirin (acetylsalicylic acid) for the 24 hour period following your injection of ACTILYSE. Your doctor may give you an injection of heparin if he/she decides it is necessary.

Your doctor will tell you how long your treatment with ACTILYSE will last. Do not stop treatment early because it will affect the management of your condition. If you have the impression that the effect of ACTILYSE is too strong or too weak, tell your doctor or pharmacist.

If you are given more ACTILYSE than you should have received

Since a healthcare provider will administer ACTILYSE, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. Possible side effects

ACTILYSE can have side effects.

Not all side effects reported for ACTILYSE are included in this leaflet. Should your general health worsen or if you experience any untoward effects after receiving

ACTILYSE, please consult your healthcare provider for advice.

The most frequent side effect with ACTILYSE is bleeding. This can be internal bleeding or superficial bleeding (normally from injection sites or damaged blood vessels). Internal bleeding can occur in the brain, gums, eyes, nose, body tissues (causing purplish bruises), liver, stomach, intestines, reproductive organs, urinary tract and around the heart. Serious internal bleeding can occur and may result in permanent disability or death.

Tell your doctor if you notice any of the following:

Frequent side-effects

- bleeding of a blood vessel resulting in a bruise (haematoma)
- bleeding in the stomach, intestine, mouth or from an ulcer, vomiting blood (haematemesis) or blood in the stools (melaena or rectal haemorrhage)
- bleeding into the body tissues causing purplish bruising (ecchymosis)
- bleeding from the urinary tract or the reproductive organs, which may lead to blood in your urine (haematuria)
- bleeding or bruising (haematoma) where the injection is given
- bleeding in the brain or skull (intracranial haemorrhage) – this may be associated with sleepiness or drowsiness, speech problems, weakness on one entire side of the body or fits.
- bleeding in the throat

Less frequent side-effects

- allergic reactions which may appear as hives (urticaria) and rash, difficulty breathing (bronchospasm), fluid under the skin and mucous membrane (angioedema), low blood pressure (causing dizziness and fainting) or shock
- bleeding in the eyes (eye haemorrhage)
- bleeding into the membranous sac surrounding the heart (pericardial haemorrhage)
- formation of blood clots in the blood vessels which can travel to other organs in the body (embolism) - the symptoms will depend on the organ affected
- bleeding in the lungs (pulmonary haemorrhage)
- bleeding in the respiratory tract, such as bleeding in the lungs resulting in coughing up blood/blood stained phlegm (haemoptysis), nosebleeds (epistaxis)
- bleeding of the gums (gingival bleeding)
- feeling like throwing-up (nausea)
- internal bleeding into the back part of the abdomen (retroperitoneal haemorrhage)
- low blood pressure (hypotension)
- irregular heart beat after the blood supply to the heart has been restored – these can be life-threatening or may lead to a heart attack.

Other side-effects

- increased body temperature (fever)
- formation of fat clots which can travel to other organs in the body (embolism) - the symptoms will depend on the organ affected
- bleeding which necessitates a blood transfusion
- throwing up (vomiting)
- bleeding in internal organs, e.g. bleeding in the liver (hepatic haemorrhage)

If you notice any side effects not mentioned in this leaflet, please inform 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 the South African Health Products Regulatory Authority (SAHPRA) via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ACTILYSE.

Suspected adverse reactions can also be reported directly to the holder of the certificate of registration using the email address pv_local_south_africa@boehringer-ingelheim.com.

5. How to store ACTILYSE

Store at or below 30 °C.

Protect the vial containing dry powder from light.

ACTILYSE should be kept in the original carton until preparation.

Store all medicines out of reach of children.

Do not use ACTILYSE after the expiry date which is printed on the label.

The reconstituted solution may be stored in a refrigerator (2 - 8 °C) for up to 24 hours and for up to 8 hours at temperatures at or below 30 °C.
From a microbiological point of view, the product should be used immediately after reconstitution. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 – 8°C.

6. Contents of the pack and other information

What ACTILYSE contains

One vial contains 50 mg alteplase (recombinant human tissue-type plasminogen activator) as the active ingredient.

The vial also contains the following inactive ingredients:

L-Arginine, phosphoric acid and polysorbate 80.

One vial of solvent contains 50 mL sterile water for injection.

What ACTILYSE looks like and contents of the pack

Each pack contains:

- one vial of ACTILYSE dry powder substance (a white to pale yellow cake),

- one vial of 50 mL solvent (sterile water for injection) and
- a sterile transfer device.

The transfer device is used for reconstituting the dry powder with the sterile water for injection.

Holder of Certificate of Registration

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This leaflet was last revised on

06 October 2026

Registration number

ACTILYSE 50 mg: U/31/229

ACTILYSE Solvent: U/32.4/230