Actilyse®

Injection with diluent

alteplase, rch

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Actilyse.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being treated with Actilyse against the benefits they expect it will have for you.

If you have any concerns about being treated with this medicine, ask your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp and may contain important information about the medicine and its use of which you should be aware.

Keep this leaflet.

You may need to read it again.

What Actilyse is used for

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 lung (pulmonary embolism)
- stroke caused by a blood clot in an artery of the brain (acute ischaemic stroke).

Actilyse contains the active ingredient alteplase. It belongs to a group of medicines called thrombolytic agents.

Actilyse works by dissolving clots in the blood vessels. These clots cause disease by interfering with normal blood flow.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you are given Actilyse

When you must not be given it

You should not be given Actilyse if you have an allergy to:

- any medicine containing alteplase (the active ingredient in Actilyse)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Because of the risk of bleeding, Actilyse should not be given to you if you have, or have had:

- a bleeding disorder at present or within the past 6 months, or a known tendency to bleed
- any history of damage to your brain or spinal cord such as tumour, aneurysm (swelling and weakening of part of a blood vessel
- childbirth or an invasive medical procedure in the past 10 days
- major surgery, including heart, head or spinal surgery, or significant trauma (including any trauma associated with heart attack) in the past 10 days
- recent trauma/injury to the head or skull
- severe and uncontrolled high blood pressure
- tumours in which the risk of bleeding is increased
- If you are taking anticoagulants (medicines used to “thin” the blood) e.g. warfarin, dabigatran, rivaroxaban or apixaban, unless tests have confirmed that the effect of the medicine has had time to wear off

- severe liver disease or liver problems
- Gastric ulcers or ulcers in the gut
- aneurysms (swelling and weakening of part of a blood vessel) in your arteries and/or known structural abnormalities in your arteries or veins
- inflammation of the lining that surrounds the heart
- inflammation of the inner lining of the heart caused by bacteria
- inflammation of the pancreas

In addition to the above medical conditions, Actilyse should not be used for the treatment of heart attack or pulmonary embolism if you have, or have had:

- a stroke caused by bleeding in the brain (condition known as haemorrhagic stroke) or a stroke of unknown origin at any time

Actilyse should not be used for the treatment of acute ischaemic stroke if you have, or have had:

- only very mild symptoms or the symptoms are rapidly improving before receiving Actilyse
- a very severe stroke
- treatment with heparin in the past 48 hours (and abnormal bleeding time)
- serious head injury/trauma within the last 3 months
- a low platelet count (platelets are blood cells involved in blood clotting)
- any signs or symptoms of bleeding in the brain or skull or any condition that increases the risk of bleeding in the brain.

Do not give this medicine to a child or adolescent under the age of 18 years.

Safety and effectiveness in children and adolescents younger than 18 years have not been established.

Actilyse should not be used after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

It is important that your doctor knows your medical history before administering Actilyse.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have, or have had, any of the following conditions:

- a previous heart attack or any other heart condition
- a previous stroke or a transient ischaemic attack (TIA)
- a family history of bleeding disorders
- any blood clotting defect
- previous stroke and you are diabetic (applies for treatment of acute ischaemic stroke)
- high blood pressure
- any recent medical procedure such as a biopsy, injection or surgery to any part of your body
- have received heart and lung resuscitation (CPR)
- if your body weight is less than 50 kg (applies for treatment of heart attack or pulmonary embolism)

If you are uncertain as to whether you have, or have had, any of these conditions you should raise those concerns with your doctor.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are over the age of 75 years.

The risks of treatment with Actilyse may be increased in any patient over 75 years of age.

Before starting treatment with Actilyse your doctor will assess other factors which may increase the risks of using Actilyse. Your doctor will take special care with Actilyse if you have or have had:

- any condition in which bleeding is a significant risk or would be particularly difficult to manage because of its location
- experienced fits or seizures at the onset of stroke (applies for treatment of acute ischaemic stroke)
- very low blood sugar (glucose) level in your blood (under 2.8mmol/L) or very high sugar level in your blood (over 22.2 mmol/L) which must be corrected before treatment with Actilyse (applies for treatment of acute ischaemic stroke)
- ever received Actilyse before.

If you have not told your doctor about any of the above, tell him/her before you are given Actilyse.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Actilyse may interfere with each other. These include:

- aspirin, heparin, warfarin or any other medicines used to "thin" the blood and prevent blood clots
- ACE inhibitors, a group of medicines used to treat high blood pressure.

These medicines may be affected by Actilyse or may affect how well it works. You may need different

amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How Actilyse is given

Actilyse will be prepared and administered to you by your doctor or by a healthcare professional. It is not for self-administration.

Treatment with Actilyse should be initiated as soon as possible after the start of your symptoms.

Actilyse is supplied as a powder and sterilised water for injections. Before use, the water for injections is added to the powder to form a solution ready for administration. This solution is given into a vein through a drip line.

How much is given

The recommended dose is 100 mg given over 90 or 180 minutes for a heart attack, or over 120 minutes for acute massive pulmonary embolism. A lower dose (1.5 mg/kg) is recommended for patients weighing less than 65 kg. No more than 100 mg should be given because it is associated with a higher risk of bleeding (especially in the brain).

For treatment of acute ischaemic stroke a dose equivalent to 0.9 mg/kg body weight is given over 60 minutes. The maximum dosage should not exceed 90 mg.

Your doctor might prescribe a different dose or duration of treatment to that described here.

If you want more information, ask your doctor.

If you are given too much (overdose)

Overdose is unlikely because Actilyse is administered under medical supervision.

Symptoms of an overdose may include bleeding.

In the case of serious bleeding, your doctor will immediately stop treatment with Actilyse and heparin. Your doctor will start appropriate treatment to control the bleeding and, if necessary, replace the lost blood.

While you are using Actilyse

Things you must not do

You should not take aspirin for the first 24 hours after treatment with Actilyse.

Your doctor may give you an injection with heparin if this is necessary.

Things to be careful of

Actilyse increases the risk of bleeding and bruising. After treatment with Actilyse medical staff will avoid giving you injections or moving you unless absolutely necessary.

Your doctor will probably continue to treat you with heparin and aspirin after treatment with Actilyse. This is to reduce the risk of more blood clots forming.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure.

If this problem continues or gets worse, talk to your doctor.

Side effects

Tell your doctor as soon as possible if you do not feel well while you are being given Actilyse.

This medicine may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

If you are over 80 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor to answer any questions you may have.

If any of the following happen, tell your doctor immediately:

- bleeding or blood clot within the head or brain. Symptoms may include collapse, sleepiness, difficulty in speaking or slurred speech, numbness or weakness of the arms or legs, headache, dizziness, visual disturbance, confusion, loss of memory, agitation, depression, weakness on one side of the body, convulsions, fits or seizures, psychosis, a severe mental condition in which the person loses contact with reality and is unable to think and judge clearly, difficulty swallowing
- bleeding from the skin, mouth, gums, nose, or eyes
- bruising
- bleeding or bruising where the injection is given
- nausea, vomiting or vomiting blood or material that looks like coffee grounds
- bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea

- blood in the urine
- coughing up blood
- changes in heart rate (fast, slow or irregular), extra heart beats, weak pulse
- chest pain, pain behind the breast bone, sometimes spreading to the neck and shoulders
- shortness of breath, tiring easily after light physical activity such as walking, waking up short of breath at night
- rapid, shallow breathing
- cold, clammy or white skin
- light-headedness
- weakness
- fluid retention in different parts of the body, often first noticed as swollen ankles and feet
- restlessness
- any symptoms of an allergic reaction (e.g. rash, itching, hives on the skin, swelling of the face, lips, mouth, tongue, throat or other parts of the body, shortness of breath, wheezing or difficulty swallowing or breathing)
- high body temperature.

Due to the life-threatening nature of the diseases for which Actilyse is used, some deaths have occurred after treatment. However, use of Actilyse in large numbers of patients has shown that when used as recommended, the benefits outweigh the risks.

There have also been reports of blockages of blood vessels following treatment with Actilyse. This can lead to organ failure (e.g. kidney failure).

Nausea and vomiting can occur after a heart attack and may or may not be increased by Actilyse.

The above list includes very serious side effects. You may need urgent medical attention.

Tell your doctor if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After being given Actilyse

Storage

Actilyse will be stored in the pharmacy or on the ward below 25ºC and protected from light.

After mixing with sterile water for injections, Actilyse should be used immediately. If not used immediately, the product may be stored in a refrigerator (2-8ºC) for up to 24 hours.

Disposal

The reconstituted solution is for single use only. Any unused solution or waste material should be disposed in accordance with the local requirements.

Product Description

What it looks like

Actilyse is the brand name of your medicine. It comes as a sterile white to off-white powder in clear glass vials containing 10 mg or 50 mg alteplase.

Actilyse powder must be mixed with sterile water for injections before use. When mixed, the resulting solution is colourless to pale yellow.

Actilyse is available as a pack containing one vial of powder and one vial of sterile water for injections.

Ingredients

Active ingredient:

Each vial of Actilyse powder contains 10 mg or 50 mg of alteplase.

Inactive ingredients:

Actilyse powder also contains:

- arginine
- nitrogen
- phosphoric acid
- polysorbate 80.

Sodium hydroxide or phosphoric acid may be added to adjust the acidity of Actilyse.

A 10 mL or 50 mL vial of sterile Water for Injections is provided for mixing with the powder.

Supplier

Actilyse is supplied in New Zealand by:

Boehringer Ingelheim (N.Z.) Limited, Auckland

This Consumer Medicine Information was updated in October 2025.