

Actilyse®

Alteplase

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Actilyse.

It does not contain all available information.

It does not take the place of talking to your doctor or pharmacist.

Consider keeping this information even after your treatment is finished.

You may want to read it again later.

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.medicines.org.au and may contain important information about the medicine and its use of which you should be aware.

To find out more about Actilyse

You should ask your doctor or pharmacist if you have any questions about your medicine or if you have any concerns about being treated with Actilyse.

What Actilyse is used for

Actilyse is intended to be used either during the early stages of a heart attack (caused by blood clots in the arteries of the heart) or in a condition of the lungs known as acute massive pulmonary embolism (caused by blood clots in the arteries of the lungs).

Actilyse is also used in the early treatment (within 4.5 hours of onset of symptoms) of a particular type of stroke known as acute ischaemic stroke. Acute ischaemic stroke occurs when a blood clot blocks a blood vessel in the brain. This leads to a sudden interruption of blood flow to an area of the brain, and results in damage of brain tissue.

The active ingredient in Actilyse is 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.

If you want more information about what Actilyse is used for, ask your doctor.

Before being treated with Actilyse

When Actilyse should not be used

You should not be treated with Actilyse if you are allergic to alteplase (the active substance in Actilyse), gentamicin or to any of the ingredients in Actilyse. These ingredients are listed in full at the end of this leaflet (See Ingredients).

If you are uncertain as to whether you have such an allergy you should raise this concern with your doctor.

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

- current bleeding or severe bleeding in the past 6 months

- a family history of bleeding disorders or a tendency to bleed
- a previous condition resulting in bleeding or suspected bleeding in the brain
- heart and lung resuscitation, childbirth, organ biopsy or an invasive medical procedure in the past 10 days
- major surgery, including heart, head or spinal surgery, or significant trauma (including trauma to the head) in the past 3 months
- severe and uncontrolled high blood pressure
- tumours in which the risk of bleeding is increased
- any blood clotting defect
- current treatment with other thrombolytic agents (medicines used for dissolving blood clots) or an anti-clotting agent (anticoagulant), such as warfarin
- certain diseases of the blood vessels, heart, brain, oesophagus, stomach/ intestine, liver, kidney or pancreas in which the risk of bleeding is increased

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
- a stroke caused by a blood clot in the artery of the brain (condition known as ischaemic stroke) or a transient ischaemic attack (TIA) in the past 6 months, unless the

symptoms of your stroke occurred within the past 4.5 hours and you are about to be treated for it

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

- experienced the symptoms of your stroke for more than 4.5 hours or if you do not know when they began
- only very mild symptoms or the symptoms are rapidly improving before receiving Actilyse
- a very severe stroke
- any signs of bleeding in the brain or any condition that increases the risk of bleeding in the brain
- fits or seizures at the onset of stroke
- treatment with heparin in the past 48 hours (and your bleeding time is abnormal)
- previous stroke or serious head injury/trauma within the last 3 months
- previous stroke and you are diabetic
- a low platelet count (platelets are blood cells involved in blood clotting)
- severe high blood pressure (over 185/110 mmHg)
- very low sugar (glucose) level in your blood (under 50 mg/dl or under 2.8 mmol/L) or very high sugar level in your blood (over 400 mg/dl or over 22.2 mmol/L)

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

Actilyse should not be used together with any other medicine which dissolves blood clots, such as streptokinase or urokinase.

Actilyse must not be used after the expiry date on the carton or vial.

Before treatment with Actilyse

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

Before being treated with Actilyse, your doctor should know if you have, or have had, any of the following conditions:

- a previous heart attack or any other heart condition
- a previous stroke caused by a blood clot in the brain or a transient ischaemic attack (TIA) more than 6 months previously (this only applies if you are being treated for heart attack or pulmonary embolism)
- diabetes mellitus
- bleeding from inside or around your eyes
- high blood pressure
- severe liver disease
- any recent medical procedure such as a biopsy or injection

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

Taking other medicines

Before Actilyse is administered your doctor should know if you are using any other medicines, and if you have ever taken:

- aspirin, heparin, warfarin or any other agent which affects the ability of the blood to clot
- ACE inhibitors (a group of medicines used for treatment of high blood pressure)

In addition, before starting treatment 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 infected veins and cannula sites or any condition in which bleeding is a significant risk or would be particularly difficult to manage because of its location

- ever received Actilyse before

The stopper of the glass vial with Actilyse powder contains natural rubber (a derivative of latex) which may cause allergic reactions.

Pregnancy

The risks of treatment with Actilyse may be increased during pregnancy.

You must tell your doctor if you are, or may be, pregnant. Actilyse should only be given to pregnant women if the need clearly outweighs the potential risk.

Breastfeeding

It is not known whether Actilyse enters the breast milk.

Special care is recommended if you are breastfeeding and you should ask for your doctor's advice in this situation.

Children

There is not enough information available to recommend the use of Actilyse in children.

Actilyse should not be used for treatment of acute ischaemic stroke in patients less than 18 years of age.

Elderly

The risks of treatment with Actilyse may be increased in patients over 70 years if they have, or have had, high blood pressure, or in any patient over 80 years of age.

Actilyse should only be given to these patients if the need clearly outweighs the potential risk.

Treatment with Actilyse

Treatment with Actilyse should begin as soon as possible after the onset of symptoms.

How Actilyse is used

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

Actilyse is a powder which must be mixed with sterilised water for injections before being given into a vein through a drip line.

For the treatment of a heart attack, you may also receive other medications to help prevent the blood vessel(s) becoming blocked again after treatment.

For the treatment of pulmonary embolism, it is recommended that heparin be given soon after treatment with Actilyse but the two medicines must be given through separate drip lines.

However, in the treatment of acute ischaemic stroke, the administration of aspirin or heparin is not recommended within the first 24 hours after Actilyse treatment.

Actilyse should only be used under the supervision of a doctor and in a setting where appropriate equipment is readily available for diagnosis and patient monitoring.

How much Actilyse is used

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.

While you are treated with Actilyse

Tell your doctor immediately if you notice any of the following while being treated with Actilyse:

- changes in heart rate (fast, slow or irregular)
- any symptoms of an allergic reaction (eg. rash, itching, hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing)
- purplish discoloration of the toes or weakness of muscles in the legs

If you have been given too much (Overdose)

Overdose is unlikely because Actilyse is administered under medical supervision.

If too much Actilyse is administered, the most likely effect is 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.

After treatment with Actilyse

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.

Side effects

You should be aware that all prescription medicines carry some

risks and that all possible risks may not be known at this stage despite thorough testing. Your doctor has weighed the risks of using Actilyse against the benefits they expect it will have for you.

Ask for the advice of your doctor or other medical staff if you have any concerns about the effects of being treated with this medicine.

The most common side effect is bleeding. This may have an effect on your blood readings.

Bleeding may be obvious if it is from the skin, gums or nose. A more serious situation is when bleeding occurs inside the body (internally), for example, bruising and stroke (bleeding in the brain).

Other symptoms such as drowsiness, difficulty speaking, inability to move parts of your body and convulsion may also occur if you experience bleeding in the brain.

Internal bleeding can occur at any site or body cavity and may result in life-threatening situations, permanent disability or death.

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.

Actilyse may cause allergic reactions but this is not common. Mild allergic reactions such as itchy skin rash have been observed. Serious or life-threatening allergic reactions, perhaps causing low blood pressure and difficulty breathing, are rare.

There have also been reports of blockages of blood vessels following treatment with Actilyse. This can lead to organ failure (eg kidney failure). These serious effects are rare.

Other side effects include nausea, vomiting, low blood pressure, irregular heart beat and fever. These events commonly occur after a heart

attack and may or may not be increased by Actilyse.

Tell your doctor as soon as possible if you experience any side effects during or after treatment with Actilyse, so that these may be properly treated.

In addition, unexpected effects, not listed above, can occur with any medicine.

You should tell your doctor if you notice anything unusual, during or after treatment with Actilyse.

Storing Actilyse

Actilyse powder must be stored below 30°C and protected from light.

After mixing with sterilised water for injections, the product should be used immediately. If not used immediately, the product may be stored in a refrigerator (2-8°C) and used within 24 hours. It is for single use only and any unused solution must be discarded.

Product Description

What the product looks like

Actilyse is the brand name of the medicine prescribed for you by your doctor. It comes as a sterile white to off-white powder in clear glass vials containing 10 mg, 20 mg or 50 mg alteplase.

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

Actilyse is sold as a pack containing one vial of powder and one vial of sterilised water for injections. Each of these packs is identified by an Australian Registration number:

- 10 mg vial - AUST R 64240
- 20 mg vial - AUST R 43375
- 50 mg vial - AUST R 17905

This number appears on the outer carton.

Not all strengths are being distributed in Australia.

Ingredients

Each vial of Actilyse powder contains 10 mg, 20 mg or 50 mg of alteplase.

The powder also contains:

- L-arginine
- phosphoric acid
- polysorbate 80

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

A 10 mL, 20 mL or 50 mL vial of sterilised Water for Injections is provided for mixing with the powder.

Manufacturer

Actilyse is made in Germany and supplied in Australia by:

Boehringer Ingelheim Pty Limited

(ABN 52 000 452 308)

78 Waterloo Road

NORTH RYDE NSW 2113

This leaflet was updated on 22 September 2010.

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