

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor.

1. Why am I being given Actilyse?

Actilyse contains the active ingredient alteplase. Actilyse is given to treat conditions caused by blood clots forming within blood vessels, including heart attack, blood clots in the lungs and stroke.

For more information, see Section [1. Why am I being given Actilyse?](#) in the full CMI.

2. What should I know before I am given Actilyse?

You should not be given Actilyse if you have ever had an allergic reaction to Actilyse or any of the ingredients listed at the end of the CMI.

Tell your doctor or nurse if you have any current or previous medical conditions including recent bleeding, are at increased risk of bleeding or have blood clotting problems, blood vessel problems, high blood pressure, serious liver problems or have had recent surgery or injury.

Talk to your doctor if you take any other medicines, are pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am given Actilyse?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Actilyse and affect how it works.

Tell your healthcare professional if you are taking any blood-thinning medicines, medicines used to treat high blood pressure, or any other medicines.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How will I be given Actilyse?

Actilyse will be prepared and administered to you by your doctor or by a healthcare professional as soon as possible after the start of symptoms.

More instructions can be found in Section [4. How will I be given Actilyse?](#) in the full CMI.

5. What should I know while being given Actilyse?

Things you should do	- Follow all instructions given to you by your healthcare professionals - Avoid moving unnecessarily to prevent bleeding or bruising
Things you should not do	You should not take aspirin for the first 24 hours after treatment with Actilyse

For more information, see Section [5. What should I know while being given Actilyse?](#) in the full CMI.

6. Are there any side effects?

If you are over 80 years of age, there is an increased probability of getting side effects.

Side effects that require urgent medical attention include: bleeding or blood clot within the head or brain which includes difficult or slurred speech, weakness in arms or legs, loss of memory or seizures; bleeding from the skin, mouth, gums, nose, eyes or back passage; nausea; vomiting; blood in the urine; coughing up blood; changes in heart rate; chest pain; shortness of breath; rapid shallow breathing; cold, clammy or white skin; light-headedness; fluid retention; allergic reaction which includes 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; fever.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about being given Actilyse. **You should also speak to your doctor if you would like further information or if you have any concerns or questions about being given Actilyse.**

Where to find information in this leaflet:

1. [Why am I being given Actilyse?](#)
2. [What should I know before I am given Actilyse?](#)
3. [What if I am taking other medicines?](#)
4. [How will I be given Actilyse?](#)
5. [What should I know while being given Actilyse?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I being given Actilyse?

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

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).

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

2. What should I know before I am given Actilyse?

Warnings

You must not be given Actilyse if you:

- are allergic to alteplase, or any of the ingredients listed at the end of this leaflet
- are under 18 years of age.

Because of the risk of bleeding, Actilyse should not be given to you 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
- serious liver problems.

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.

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
- mild neurological symptoms or when 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).

Check with your doctor if you:

- have or have had any of the following conditions:
 - allergies to any other medicines, foods, preservatives or dyes

- o a previous heart attack or any other heart condition
 - o 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)
 - o diabetes mellitus
 - o bleeding from inside or around your eyes or visual disturbances
 - o high blood pressure
 - o severe liver disease
 - o any recent medical procedure such as a biopsy or injection
 - o any condition in which bleeding is a significant risk or would be particularly difficult to manage because of its location
 - o any infected veins and cannula sites
- ever received Actilyse before

Tell your doctor if you are over the age of 70 years.

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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or are breastfeeding.

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

Children

Actilyse must not be given to a child under the age of 18 years. The safety and effectiveness in this age group has not been established.

3. What if I am taking other medicines?

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

Some medicines may interfere with Actilyse and affect how it works.

Medicines that may increase the risk of bleeding include:

- aspirin, heparin, warfarin or any other medicines used to "thin" the blood and prevent blood clots.

Medicines that may increase the risk of a serious allergic reaction include:

- ACE inhibitors, a group of medicines used to treat high blood pressure.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Actilyse.

4. How will I be given Actilyse?

How much you will be given

- The recommended dose is 100 mg given over 90 or 180 minutes for a heart attack, or over 120 minutes for 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.

Ask your doctor if you want more information.

How you will be given Actilyse

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

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.

When you will be given Actilyse

You should be treated with Actilyse as soon as possible after the onset of your symptoms.

If you are given too much Actilyse

An 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.

5. What should I know while being given Actilyse?

Things you should 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.

Things you should 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.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Serious side effects

Serious side effects	What to do
Bleeding-related problems: • 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 • vomiting blood or material that looks like coffee grounds • bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea	Tell your doctor immediately if you notice any of these serious side effects.

Serious side effects	What to do
• blood in the urine • coughing up blood Signs of heart problems: • changes in heart rate (fast, slow or irregular), extra heart beats, weak pulse • chest pain, pain behind the breastbone, sometimes spreading to the neck and shoulders • 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 Breathing problems: • shortness of breath, tiring easily after light physical activity such as walking, waking up short of breath at night • rapid, shallow breathing Signs of an allergic reaction: • rash, itching or 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 Other side effects: • nausea and vomiting • high body temperature (fever)	Tell your doctor immediately if you notice any of these serious side effects.

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).

Tell your doctor if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

What Actilyse contains

Active ingredient (main ingredient)	alteplase (10 mg, 20 mg or 50 mg)
Other ingredients (inactive ingredients)	• arginine • phosphoric acid • polysorbate 80 • nitrogen

You should not be given this medicine if you are allergic to any of these ingredients.

What Actilyse looks like

Actilyse is the brand name of your medicine.

It comes as a sterile white to off-white powder in a clear glass vial. Actilyse powder must be mixed with sterile Water for Injections before use. When mixed, the resulting solution is clear, and colourless to pale yellow.

The reconstituted solution contains 1 mg of alteplase per mL.

Actilyse is available as a pack containing one vial of powder and one vial of sterilised Water for Injections.

Actilyse is available in three strengths:

- Actilyse 10 mg: One vial of powder with 10 mg alteplase and one vial with 10 mL of sterilised Water for Injections (AUST R 64240)
- Actilyse 20 mg: One vial of powder with 20 mg alteplase and one vial with 20 mL of sterilised Water for Injections (AUST R 43375)*
- Actilyse 50 mg: One vial of powder with 50 mg alteplase and one vial with 50 mL of sterilised Water for Injections (AUST R 17905)

*Not distributed in Australia

Who distributes Actilyse

Actilyse is supplied in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney NSW

www.boehringer-ingelheim.com.au

This leaflet was prepared in December 2025.

* Actilyse is a registered trademark of Boehringer Ingelheim