

Consumer Medicine Information (CMI) summary

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

1. Why am I being given Actilyse Cathflo?

Actilyse Cathflo contains the active ingredient alteplase. It belongs in the group of medicines called thrombolytic agents. Actilyse Cathflo is used to clear catheters which are blocked by blood clots. It works by dissolving the blood clots in blocked catheters. For more information, see Section [1. Why am I being given Actilyse Cathflo?](#) in the full CMI.

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

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

Tell your doctor if you have or have had conditions such as bleeding in any part of the body, a bleeding disorder, severe liver or kidney disease, any condition for which bleeding is a significant risk or would be difficult to manage because of its location.

Tell your doctor if in the past 48 hours you have had surgery, delivery of a baby, biopsy (procedure for obtaining a tissue specimen) or puncture of the skin.

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

This medicine must not be used to clear blocked catheters in preterm babies.

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

3. What if I am taking other medicines?

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

Tell your healthcare professional if you are taking any blood-thinning medicines or medicines to prevent blood clots (antiplatelets or anticoagulants), medicine to treat high blood pressure and some other heart conditions (Angiotensin Converting Enzyme Inhibitors) 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 Cathflo?

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

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

5. What should I know while being given Actilyse Cathflo?

Things you should do	<ul style="list-style-type: none">Follow all instructions given to you by your healthcare professionalTell your doctor or nurse as soon as possible if you do not feel well while you are being given Actilyse Cathflo.
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For more information, see Section [5. What should I know while being given Actilyse Cathflo?](#) in the full CMI.

6. Are there any side effects?

If you are over 65 years of age with conditions known to increase the risk of bleeding you may have an increased chance of getting side effects.

Side effects that may require urgent medical attention include: infection of the blood (sepsis) which includes symptoms such as fever, chills, headache, confusion and rapid breathing; bleeding from the stomach or intestine which includes symptoms such as vomiting blood, bleeding from the back passage or black sticky bowel motions; bleeding from the nose; bleeding from the injection site; allergic reaction which includes symptoms such as 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.

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.

Actilyse® Cathflo®

Active ingredient: *alteplase*

Consumer Medicine Information (CMI)

This leaflet provides important information about Actilyse Cathflo. **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 Cathflo.**

Where to find information in this leaflet:

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

1. Why am I being given Actilyse Cathflo?

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

Actilyse Cathflo is used to clear catheters which are blocked by blood clots.

It works by dissolving the blood clots in blocked catheters.

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

Warnings

You must not be given Actilyse Cathflo if you are allergic to alteplase or any of the ingredients listed at the end of this leaflet.

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

You should tell your doctor if you have, or have had any of the following conditions:

- allergies to any other medicines, foods, preservatives or dyes
- bleeding in any part of the body
- a bleeding disorder or a tendency to bleed or bruise more easily than normal
- severe liver or kidney disease
- any condition for which bleeding is a significant risk or would be particularly difficult to manage because of its location.

In addition to the above, you must tell your doctor if you have had any of the following conditions in the past 48 hours, which increases your risk of bleeding:

- surgery
- delivery of a baby

- biopsy (a procedure for obtaining a tissue specimen)
- puncture of the skin.

Speak to your doctor if you are uncertain as to whether any of these conditions apply to you.

Before starting treatment with Actilyse Cathflo your doctor will assess other factors which may increase the risks of using Actilyse Cathflo.

Your doctor will take special care with Actilyse Cathflo if there is or may be an infection located in the catheter.

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?](#)

Tell your doctor if you are over the age of 65 years.

The risks of treatment with Actilyse Cathflo may be increased in patients over 65 years if they have conditions known to increase the risk of bleeding.

This medicine must not be used to clear blocked catheters in preterm babies.

Safety and effectiveness in preterm babies have not been established.

Pregnancy and breastfeeding

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.

3. What if I am taking other medicines?

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

Some medicines may interfere with Actilyse Cathflo and affect how it works. These include:

- Antiplatelets such as aspirin and anticoagulants such as heparin and warfarin or any other medicines used to "thin" the blood and prevent blood clots
- Angiotensin Converting Enzyme (ACE) inhibitors, a group of medicines used to treat high blood pressure and some other heart conditions

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

4. How will I be given Actilyse Cathflo?

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

Actilyse Cathflo is supplied as a powder and must be mixed with sterile water for injections to form a solution ready for administration. This solution is filled into the blocked catheter. Actilyse Cathflo should not be mixed with other medicines.

How much will you be given

The dose you are given depends on your body weight.

For patients weighing 30 kg or more, the maximum recommended dose of Actilyse Cathflo is 2 mg for clearance of blocked catheters.

For patients weighing less than 30 kg a lower dose (not exceeding 2 mg in total) is recommended and the dose will depend on the internal lumen volume of the catheter.

How will you be given Actilyse Cathflo

Your doctor will administer Actilyse Cathflo. For clearance of blocked catheters, the appropriate dose of Actilyse Cathflo is filled into the blocked catheter.

After 30 minutes, your doctor will check if the blocked catheter has been cleared. If the catheter has been cleared, treatment with Actilyse Cathflo will be stopped. If the blocked catheter is not yet cleared after 30 minutes, Actilyse Cathflo will remain in the blocked catheter for another 90 minutes.

After treatment, Actilyse Cathflo is removed from the catheter. The catheter is rinsed with sterile normal saline solution.

If the catheter is still blocked after your first treatment with Actilyse Cathflo, the whole procedure may be repeated once.

If you are given too much Actilyse Cathflo

Overdose is unlikely because Actilyse Cathflo 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 Cathflo and remove Actilyse Cathflo from the catheter. 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 Cathflo?

Things you should do

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

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 65 years of age with conditions known to increase the risk of bleeding you may have an increased chance of getting side effects.

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

Serious side effects

Serious side effects	What to do
<p>Infection of the blood (sepsis) caused by release of an infection from the catheter to the blood vessels. Symptoms of sepsis include:</p> <ul style="list-style-type: none"> • fever • chills • headache • confusion • rapid breathing <p>Bleeding related problems:</p> <ul style="list-style-type: none"> • bleeding from the stomach or intestine. Symptoms may include vomiting blood, bleeding from the back passage or black sticky bowel motions • bleeding from the nose • bleeding from the injection site <p>Signs of an allergic reaction:</p> <ul style="list-style-type: none"> • shortness of breath • wheezing or difficulty breathing • swelling of the face, lips, mouth, tongue, throat or other parts of the body • rash, itching or hives on the skin. 	<p>Tell your doctor immediately if you notice any of these serious side effects.</p>

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

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

Other side effects not listed above may also 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 <https://www.tga.gov.au/safety/reporting-problems>. By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

What Actilyse Cathflo contains

Active ingredient (main ingredient)	alteplase (2 mg)
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Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • arginine • phosphoric acid • polysorbate 80 • nitrogen.
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You should not be given this medicine if you are allergic to any of these ingredients.

What Actilyse Cathflo looks like

Actilyse Cathflo is the brand name of your medicine.

Actilyse Cathflo comes as a sterile, white to off-white powder in a clear glass vial containing 2 mg alteplase (AUST R 142795).

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

Actilyse Cathflo is available in the following pack sizes:

- one vial of Actilyse Cathflo powder*
- five vials of Actilyse Cathflo powder

* not currently distributed in Australia

Who distributes Actilyse Cathflo

Actilyse Cathflo 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 November 2024.

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