

Actilyse® Cathflo® 2 mg powder for solution for injection and infusion

Alteplase



Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Actilyse Cathflo is and what it is used for
2. What you need to know before you receive Actilyse Cathflo
3. How is Actilyse Cathflo administered
4. Possible side effects
5. How to store Actilyse Cathflo
6. Contents of the pack and other information

1. What Actilyse Cathflo is and what it is used for

The active substance in Actilyse Cathflo is alteplase. It belongs to a group of medicines called thrombolytic agents. These medicines act by dissolving blood clots.

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

2. What you need to know before you get Actilyse Cathflo

You should not receive Actilyse Cathflo

- if you are allergic (hypersensitive) to the active substance alteplase, to gentamicin (a trace residue from the manufacturing process), to natural rubber (also called latex which is part of the packaging material) or to any of the other ingredients of this medicine (listed in section 6).

Your doctor will take special care with Actilyse Cathflo

- if you have had any allergic reaction other than a sudden life-threatening allergic reaction (severe hypersensitivity) to the active substance alteplase, to gentamicin (a trace residue from the manufacturing process), to natural rubber (also called latex which is part of the packaging material) or to any of the other ingredients of this medicine (listed in section 6).
- if you have a bleeding in any part of the body
- if in the past 48 hours you have had a condition that increases your risk of bleeding, including:
 - surgery
 - biopsy (a procedure for obtaining a tissue specimen)
 - puncture
 - delivery of a baby
- if you have a bleeding disorder or tendency to bleed
- if you have severe liver or kidney disease
- if a blood vessel located close to the catheter is blocked by blood clots (venous thrombosis)
- if there is or may be an infection located in the catheter

Other medicines and Actilyse Cathflo

Tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. It is particularly important that you tell your doctor if you are taking or have recently taken:

- any medicines which are used to “thin” the blood, including:
 - acetylsalicylic acid
 - warfarin
 - coumarin
 - heparin
- certain medicines used to treat high blood pressure (ACE inhibitors).

Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine. Your doctor will only give you Actilyse Cathflo if the possible benefit outweighs the possible risk to your baby.

Actilyse Cathflo may contain gentamicin as trace residue from the manufacturing process; the packaging contains natural rubber (latex).

3. How is Actilyse Cathflo administered

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

The dose you are given depends on your body weight. The maximum dose of Actilyse Cathflo is 2 mg but will be lower if you weigh less than 30 kg.

Actilyse Cathflo is filled in the blocked catheter. After 30 min your doctor will check if the catheter has already been cleared. If this is the case, treatment with Actilyse Cathflo will be stopped. If this is not yet the case, the product will remain in the catheter for another 90 min.

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

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

Actilyse Cathflo should not be mixed with other medicines.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The side effects described below have been experienced by people given Actilyse Cathflo:

Uncommon (occurs in less than 1 in 100 patients receiving the medicine)

- release of an infection from the catheter to the blood vessels leading to blood poisoning (sepsis)
- damage to the catheter such as:
 - blockage
 - leakage
 - burst

Rare (occurs in less than 1 in 1,000 patients receiving the medicine)

- fever

In principle, all undesirable effects as found for the application of Actilyse (10, 20, 50 mg of alteplase) for heart attacks, pulmonary embolism or stroke may also occur during treatment of catheters blocked by blood clots. This is however only possible in cases where Actilyse Cathflo (2 mg of alteplase) reaches the blood circulation. The following side effects may occur: e.g. bleeding (haemorrhage), sudden blocking of a blood vessel (embolism), allergic (hypersensitivity/anaphylactoid) reactions, blood pressure decreased, nausea, vomiting, body temperature increased. However none of these side effects has ever been observed with Actilyse Cathflo so far. Due to the small amount of medicine used, these side effects are very unlikely to occur with Actilyse Cathflo (2 mg) – apart from allergic reactions for which a small amount may be sufficient. When using the product Actilyse (10, 20, 50 mg of alteplase), allergic reactions have been observed rarely.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store Actilyse Cathflo

Normally you will not be asked to store Actilyse Cathflo as it will be given to you by your doctor.

Keep this medicine out of the sight and reach of children.

Store in a refrigerator (2 – 8 °C).
Store in the original package in order to protect from light.

Do not use this medicine after expiry date which is stated on the vial label and the carton. The expiry date refers to the last day of that month.

Reconstituted solution

The reconstituted solution has been demonstrated to be stable for 24 hours at 2 °C – 8 °C and for 8 hours at 25 °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 Cathflo contains

- The active substance is alteplase. Each vial contains 2 mg (corresponding to 1,160,000 IU) alteplase. Alteplase is produced by recombinant DNA technique using a Chinese hamster ovary cell-line.
- The other ingredients are arginine, phosphoric acid (for pH-adjustment) and polysorbate 80.
- The rubber stopper of the packaging material contains natural rubber (latex)

What Actilyse Cathflo looks like and contents of the pack

Actilyse Cathflo is a powder for solution for injection and infusion. Each pack contains five vials, each with 2 mg alteplase.

Marketing Authorisation Holder

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