PACKAGE LEAFLET: INFORMATION FOR THE USER

Actilyse Cathflo 2 mg, poeder voor oplossing voor injectie en infusie

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

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 alteplase 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 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
If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor for advice. Your doctor will only give you Actilyse Cathflo if the possible benefit outweighs the possible risk to your baby.

3. How is Actilyse Cathflo administered

Actilyse Cathflo will be prepared and administered to you by your doctor or by a healthcare 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 via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

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.

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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In het register ingeschreven onder:
Actilyse Cathflo 2 mg, poeder voor oplossing voor injectie en infusie: RVG 103374

Deze bijsluiter is voor het laatst goedgekeurd in september 2024

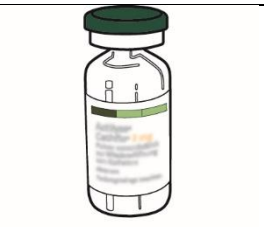
The following information is intended for medical or healthcare professionals only:

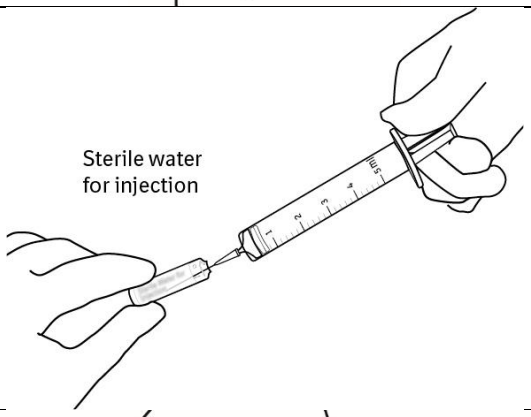
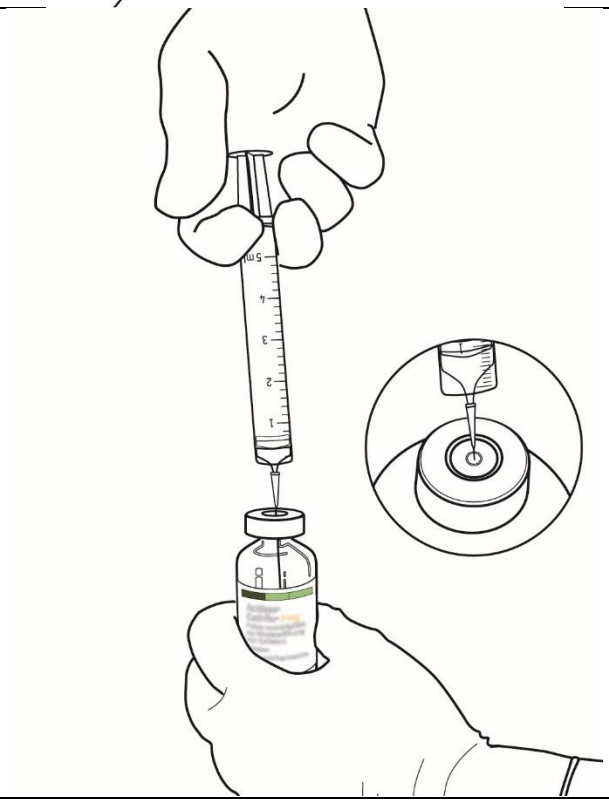
Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

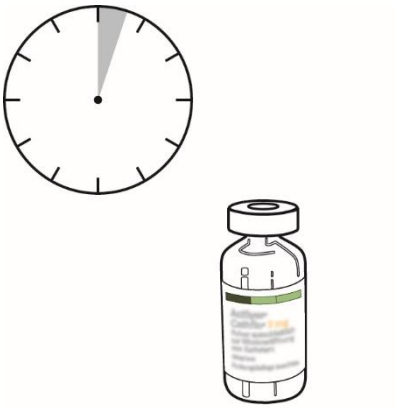
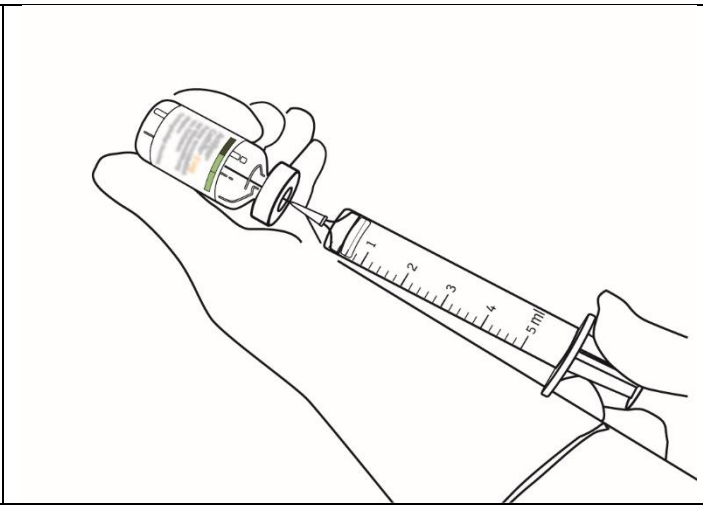
Instructions for reconstitution

The 2 mg vial of alteplase is not indicated for use in myocardial infarction, acute pulmonary embolism or acute ischaemic stroke (due to risk of massive underdosing). Only 10, 20 or 50 mg vials are indicated for use in those indications.

The 2 mg vial (supplied with an overage) is dissolved with 2.2 mL sterilised water for injection to obtain a final concentration of 1 mg alteplase per ml.

1	Reconstitute immediately before administration.	
2	Remove the protective cap on the vial containing Actilyse Cathflo dry substance by flipping it up with a thumb.	

3	Swab the rubber top of the vial with an alcohol wipe.	
4	Withdraw 2.2 mL sterilised water for injection by use of a syringe with a suitable measuring precision under aseptic conditions.	
5	Transfer the 2.2 mL sterilised water for injection into the Actilyse Cathflo vial by introducing the needle vertically into the middle of the rubber stopper, directing the diluent stream into the powder.	

6	Take the vial with reconstituted Actilyse Cathflo and swirl gently to dissolve any remaining powder, but do not shake, as this will produce foam. If there are bubbles, let the solution stand undisturbed for a few minutes to allow them to disappear.	 
7	The reconstituted solution consists of 1 mg/mL alteplase. It should be clear and colourless to pale yellow and should not contain any particles.	
8	Remove the amount required using a needle and a syringe.	
9	Use immediately. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.	

The reconstituted solution should then be instilled into the occluded central venous access device. It may be diluted further with sterile sodium chloride 9 mg/ml (0.9 %) solution for injection up to a minimal concentration of 0.2 mg/ml since the occurrence of turbidity of the reconstituted solution cannot be excluded.

A further dilution of the 1 mg/mL reconstituted solution with sterilised water for injections or in general, the use of carbohydrate infusion solutions, e.g. dextrose is not recommended due to increasing formation of turbidity of the reconstituted solution. Actilyse Cathflo should not be mixed with other medicinal products in the same catheter (not even with heparin).

For incompatibilities see section 6.2 of the SmPC.

For storage conditions, please see section 5 of this leaflet.

Instructions for administration in occluded central venous access devices including those used for haemodialysis

1. Reconstitute the content of an injection vial to a final concentration of 1 mg alteplase per ml. For catheters with a lumen volume greater than 2 ml, the reconstituted solution can be further diluted with sterile sodium chloride 9 mg/ml (0.9 %) solution for injection to the desired volume. I.e. for a catheter with internal volume of 2.5 ml the total dose of Actilyse Cathflo would be 2.0 mg in a volume of 2.5 ml.

2. Instil the appropriate dose of Actilyse Cathflo into the occluded central venous access device.

3. After 30 minutes of dwell time, assess catheter functionality by attempting to aspirate blood. If the catheter is functional, go to Step 6. If the catheter is not functional, go to Step 4.

4. After 120 minutes of dwell time, assess catheter functionality by attempting to aspirate blood and catheter contents. If the catheter is functional, go to Step 6. If the catheter is not functional, go to Step 5.

5. If catheter functionality is not restored after the first dose, a second dose of equal amount may be instilled. Repeat the procedure beginning with Step 1. If after a second dose of alteplase the catheter functionality has not been restored consider catheter replacement.

6. If catheter functionality has been restored, aspirate 4–5 ml of blood in patients weighing 10 kg or more, or 3 ml in patients with a body weight below 10 kg to remove Actilyse Cathflo and residual clot, and gently irrigate the catheter with sterile sodium chloride 9 mg/ml (0.9 %) solution for injection.