

ACTILYSE[®] CATHFLO[®]

alteplase (rch) 2 mg
powder for injection



Instructions for Reconstitution



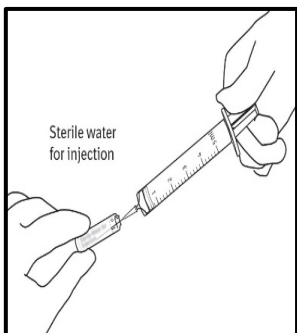
1. Reconstitute immediately before administration.



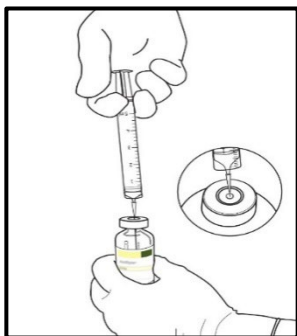
2. Remove the protective cap on the vial containing ACTILYSE CATHFLO dry substance by flipping it up with a thumb.



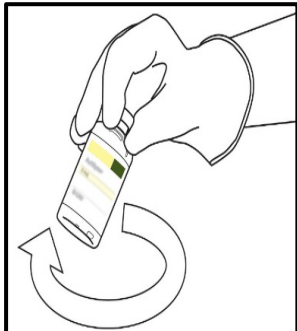
3. Swab the rubber top of the vial with an alcohol wipe.



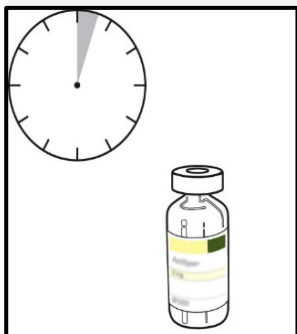
4. Aseptically withdraw 2.2 mL sterilised Water for Injection.



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.

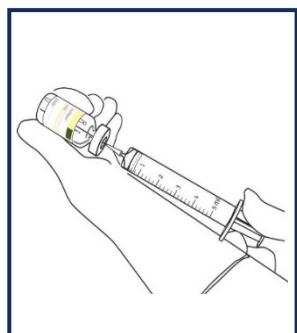


6. Take the vial with reconstituted ACTILYSE CATHFLO and swirl gently to dissolve any remaining powder, but do not shake, as this will produce foam.



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 ACTILYSE CATHFLO. It should be clear and colourless to pale yellow and it should not contain any particles.



8. Remove the amount required using a needle and a syringe.

9. Use immediately.
Dispose of any unused solution.

Instructions for Dilution

The reconstituted solution (1 mg alteplase per mL) may be diluted further, immediately before instillation, with sterile physiological saline solution (0.9% Sodium Chloride for Injection) up to a minimal concentration of 0.2 mg alteplase per mL. Further dilution of the reconstituted solution with sterile physiological saline solution (0.9% Sodium Chloride for Injection) below a minimal concentration of 0.2 mg alteplase per mL is not recommended since the occurrence of turbidity of the reconstituted solution cannot be excluded.

A further dilution of the 1 mg/mL reconstituted solution with sterile Water for Injection, carbohydrate infusion solutions (e.g. glucose) or preservative containing solutions is not recommended due to increasing formation of turbidity of the reconstituted solution.

Excessive agitation during dilution should be avoided; mixing should be accomplished with gentle swirling and/or slow inversion.

No other medication should be added to ACTILYSE CATHFLO solution. Because ACTILYSE CATHFLO contains no preservatives, it should be reconstituted immediately before use.

Instructions for Instillation of the ACTILYSE CATHFLO Solution into the Catheter

1. Reconstitute the contents of the ACTILYSE CATHFLO 2 mg injection vial to the final concentration of 1 mg alteplase per mL (see Instructions for Reconstitution). For catheters with a lumen volume greater than 2 mL, ACTILYSE CATHFLO can be further diluted with sterile physiological saline solution (0.9% Sodium Chloride for Injection) to the desired volume (see Instructions for Dilution).
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 at 120 minutes of dwell time 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 ACTILYSE CATHFLO the catheter functionality has not been restored, consider the need for catheter replacement.
6. If catheter functionality has been restored, aspirate 4-5 mL of blood in patients with a body weight of 10 kg or more, or 3 mL in patient with a body weight of less than 10 kg, to remove ACTILYSE CATHFLO and residual clot, and gently irrigate the catheter with sterile physiological saline solution (0.9% Sodium Chloride for Injection).

Actilyse® and Cathflo® are registered trademarks of Boehringer Ingelheim
© Boehringer Ingelheim Pty Limited 2024