Cathflo Activase (alteplase) 2 mg is the only lytic FDA approved for the restoration of function to central venous access devices (CVADs)

Preparation of solution

After WASHING hands, using aseptic technique, reconstitute Cathflo to a final concentration of 2 mg/2 mL:

1. Aseptically WITHDRAW 2.2 mL of Sterile Water for Injection, USP (diluent is not provided). Do not use Bacteriostatic Water for Injection, USP.

2. INJECT the 2.2 mL of Sterile Water for Injection, USP, into the Cathflo vial, directing the diluent stream into the powder. Slight foaming is not unusual; let the vial stand undisturbed to allow large bubbles to dissipate.

3. Mix by gently SWIRLING until the contents are completely dissolved. Complete dissolution should occur within 3 minutes. DO NOT SHAKE. The reconstituted preparation results in a colorless to pale yellow transparent solution at a pH of approximately 7.3.

Note: Store lyophilized Cathflo at refrigerated temperature (2°C–8°C/36°F–46°F). Cathflo contains no antibacterial preservatives and should be reconstituted immediately before use. The solution may be used for intracatheter instillation within 8 hours following reconstitution when stored at 2°C to 30°C (36°F–86°F).

Indication

Cathflo Activase (Alteplase) is indicated for the restoration of function to central venous access devices as assessed by the ability to withdraw blood.

Important Safety Information

Cathflo Activase should not be administered to patients with known hypersensitivity to Alteplase or any component of the formulation.

In clinical trials, the most serious adverse events reported after treatment were sepsis, gastrointestinal bleeding, and venous thrombosis. Cathflo Activase should be used with caution in the presence of known or suspected infections in the catheter.

Please see accompanying full Prescribing Information for additional Important Safety Information.


Genentech
A Member of the Roche Group

www.cathflo.com
Administration

After WASHING hands and applying gloves:

4. INSPECT the product prior to administration for foreign matter and discoloration. Solution should be inspected immediately before use.

5. WITHDRAW 2 mL (2 mg) of reconstituted solution from the vial.

6. SCRUB the hub. Apply vigorous friction to the hubs for 15 to 30 seconds.

7. INSTILL the appropriate dose of Cathflo into the occluded catheter using an appropriately sized syringe (see dosing chart below).

8. After 30 minutes of DWELL time, assess the catheter function by attempting to aspirate blood. If the catheter is functional, go to step 10; if not functional, go to step 9.

9. ASSESS catheter function after a total of 120 minutes of dwell time by attempting to aspirate blood. If catheter is functional, go to step 10. If catheter is still occluded, a second dose of equal amount may be instilled. Repeat steps 1 through 8.

10. If catheter function has been restored, ASPIRATE 4 mL to 5 mL of blood in patients ≥10 kg or 3 mL in patients <10 kg to remove Cathflo and residual clot. Then gently irrigate the catheter with 0.9% Sodium Chloride, USP. Any unused solution should be discarded.

Dosing with Cathflo Activase (alteplase) 2 mg

<table>
<thead>
<tr>
<th>Patient weight</th>
<th>Cathflo dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥30 kg (66 lb)</td>
<td>2 mg in 2 mL</td>
</tr>
<tr>
<td>&lt;30 kg (66 lb)</td>
<td>110% of the internal lumen volume of CVAD, not to exceed 2 mg in 2 mL</td>
</tr>
</tbody>
</table>

No other medication should be added to solutions containing Cathflo.

Please see Indication and Important Safety Information on reverse. Please also see accompanying full Prescribing Information.