Pediatric FDA-approved dosing with Cathflo Activase (alteplase)\(^1\)

<table>
<thead>
<tr>
<th>Patient weight (lb)</th>
<th>Cathflo dose</th>
</tr>
</thead>
<tbody>
<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>
<tr>
<td>≥30 kg (66 lb)</td>
<td>2 mg in 5 mL</td>
</tr>
</tbody>
</table>

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

Please see additional Important Safety Information on reverse side.

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\(^1\) Single-use vial

After performing hand hygiene and donning gloves, aseptically reconstitute using 2.2 mL sterile water for injection and inspect solution for foreign matter and discoloration.

1. After washing hands and applying gloves:
   - INSTILL the appropriate dose of Cathflo into the occluded catheter using a 10-mL syringe (see dosing chart below).

2. After 30 minutes of DWELL time, assess catheter function by attempting to aspirate blood. If the catheter is functional, go to step 5; if not functional, go to step 4.

3. ASSESS catheter function after a total of 120 minutes of dwell time by attempting to aspirate blood. If catheter is functional, go to step 5. If catheter is still occluded, a second dose of equal amount may be instilled. Repeat steps 1 through 3.

4. 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 discase aspirate, and flush catheter with 0.9% Sodium Chloride, USP. Any unused solution should be discarded.

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www.cathflo.com

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### Cathflo® Activase® (alteplase) in Pediatrics

Dosing and Administration

Cathflo® is the only FDA-approved treatment of thrombotically occluded pediatric catheters.

*If a thrombotic occlusion is suspected, the treatment is timely administration of alteplase (Cathflo Activase), a thrombolytic that is the only FDA-approved agent for the treatment of dysfunctional catheters.*

— AVA Best Practice Guidelines in the Care and Maintenance of Pediatric Central Venous Catheters, 2015, page 14

**Measure the internal lumen volume to determine the Cathflo dose for pediatric patients**

<table>
<thead>
<tr>
<th>Device</th>
<th>Device Ranges</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peripherally inserted central catheter (PICC)</td>
<td>Device priming volume ranges from 0.06 to 0.6 mL. Check manufacturer guidelines</td>
</tr>
<tr>
<td>Tunneled and nontunneled</td>
<td>Device priming volume ranges from 0.12 to 1.3 mL. Check manufacturer guidelines</td>
</tr>
<tr>
<td>Implanted port</td>
<td>Device priming volume ranges from 0.8 to 2 mL. Check manufacturer guidelines</td>
</tr>
</tbody>
</table>

*Dependent on the CVAD manufacturer, size, number of lumens, add-on device, patient weight, and final length of the catheter; the priming volume will vary.

**Important Safety Information (cont'd)**

**Precautions**

**General**

Certain causes of catheter dysfunction should be considered before treatment with Cathflo Activase (e.g., catheter malposition, mechanical failure, constriction by a suture and lipid deposits or drug precipitates within the catheter lumen). These types of conditions should be considered before treatment with Cathflo Activase.

**Bleeding**

The most frequent adverse reaction associated with all thrombolytics in all approved indications is bleeding.

Should serious bleeding in a critical location (e.g., intracranial, gastrointestinal, retroperitoneal, pericardial) occur, treatment with Cathflo Activase should be stopped and the drug should be withdrawn from the catheter.

**Infections**

Cathflo Activase should be used with caution in the presence of known or suspected infection in the catheter.

**Hypersensitivity**

Hypersensitivity, including urticaria, angioedema and anaphylaxis, has been reported in association with use of Cathflo Activase. Monitor patients treated with Cathflo Activase for signs of hypersensitivity and treat appropriately if necessary.

**Adverse Reactions**

In clinical trials, the most serious adverse events reported after treatment were sepsis, gastrointestinal bleeding, and venous thrombosis.

Please see Indication and Important Safety Information on reverse side. Please see accompanying full Prescribing Information for additional important safety information.

**References:**

1. Cathflo Prescribing Information. Genentech USA, Inc.

### Important Safety Information (cont'd)

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