PRODUCT MONOGRAPH

PR Cathflo®

alteplase, recombinant

Lyophilized Powder for Intracatheter Instillation - 2 mg

Fibrinolytic Agent

Hoffmann-La Roche Limited
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PART III: CONSUMER INFORMATION

PRCathflo®
(alteplase, recombinant)

This leaflet is part III of a three-part "Product Monograph" published when Cathflo was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Cathflo. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
Cathflo (alteplase, recombinant) is used for getting back to normal function to central venous access devices.

What it does:
ACTIVASE rt-PA when introduced into the blood circulation, will bind to fibrin (protein that prevents the flow of blood) in blood clots and converts the entrapped plasminogen to plasmin (which breakdowns fibrin clots).

When it should not be used:
Patients who are hypersensitive to alteplase, to any ingredient in the formulation, or component of the container.

What the medicinal ingredient is:
alteplase, recombinant

What the important nonmedicinal ingredients are:
L-arginine, polysorbate 80 and phosphoric acid

What dosage forms it comes in:
- Cathflo (alteplase, recombinant) is supplied as a sterile, lyophilized powder in 2-mg vials.
- Each carton contains ten 2-mg vials of Cathflo.
- Each reconstituted vial will deliver 2 mg of Cathflo, at a pH of approximately 7.3.

WARNINGS AND PRECAUTIONS

Your healthcare professional will ensure the following:
- Not to apply vigorous suction when attempting to determine catheter occlusion to prevent damage to the vascular wall or collapse of soft-walled catheters.
- To avoid excessive pressure when Cathflo (alteplase, recombinant) is instilled into the catheter. Such force could cause rupture of the catheter or expulsion of the clot into the circulation.
- Caution with patients who have:
    - a bleeding disorder or recent history of bleeding
    - had recent major surgery
    - severe liver failure
    - or are at high risk for embolic complications (e.g., blood clots breaking off and traveling through the blood causing vascular obstruction)

If serious bleeding in a critical location occurs (e.g. within the skull, gut, stomach, heart), treatment with Cathflo should be stopped and the drug should be withdrawn from the catheter.

Cathflo should be used with caution in the presence of known or suspected infection in the catheter. As with all catheterization procedures, aseptic technique must be used.

Hypersensitivity might occur during treatment of occluded catheters in cases where Cathflo reaches the systemic circulation. In the event that an anaphylactoid reaction was to occur upon the administration of Cathflo, appropriate therapy should be initiated.

Special Populations
Pregnant Women:
The use of Cathflo in pregnant women has not been studied. Cathflo should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Women:
It is not known whether Cathflo is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Cathflo is administered to a nursing woman.

Pediatrics:

Alteplase has been studied in patients from 2 to 16 years of age. No study drug related adverse events were observed in these pediatric patients.

Alteplase has not been studied in patients who are younger than 2 years of age or who weigh less than 10 kg.

Geriatrics:
The effect of alteplase on common age-related illnesses has not been studied. In general, caution should be used in geriatric patients with conditions known to increase the risk of bleeding.

INTERACTIONS WITH THIS MEDICATION

The interaction of Cathflo with other drugs has not been formally studied. Using other drugs affecting coagulation and/or platelet function at the same time as Cathflo has not been studied.

PROPER USE OF THIS MEDICATION

Cathflo (alteplase, recombinant) is for intracatheter administration (instillation into the dysfunctional catheter) by a healthcare professional.

Recommended Dose and Dosage Adjustment
For patients weighing 30 kg and over, the dose of Cathflo® is 2 mg, with a dose volume of 2 mL. The recommended dose for patients weighing less than 30 kg is 110% of the internal lumen volume of their CVAD, not to exceed 2 mL. There is no efficacy and safety information on dosing in excess of 2 mg per dose. Studies have not been performed with total doses greater than 4 mg (two 2-mg doses).

Refer to Product Monograph Part I – Health Professional Information – DOSAGE AND ADMINISTRATION section for additional Preparation and Administration information.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Hypersensitivity
Hypersensitivity might occur during treatment of occluded catheters in cases where Cathflo reaches the systemic circulation. In the event that an anaphylactoid reaction was to occur upon the administration of Cathflo®, appropriate therapy should be initiated.

For any unexpected effects while taking Cathflo ***contact your doctor or pharmacist.***

HOW TO STORE IT

- Store lyophilized Cathflo at refrigerated temperature 2°C to 8°C.
- Do not use beyond the expiration date on the vial.
- Protect the lyophilized material during extended storage from excessive exposure to light.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at
www.healthcanada.gc.ca/medeffect
Call toll-free at 1-866-234-2345
Complete a Canada Vigilance Reporting Form and:

- **Fax toll-free to 1-866-678-6789, or**
- **Mail to: Canada Vigilance Program**
  Health Canada
  Postal Locator 1908C
  Ottawa, Ontario
  K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph,

prepared for health professionals can be found at: http://www.rochecanada.com or by contacting the sponsor, Hoffmann-La Roche Limited at: 1-888-762-4388

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