

Cathflo Activase (alteplase) 2 mg is the only FDA-approved thrombolytic agent for the restoration of function to CVADs as assessed by the ability to withdraw blood¹



Key societies support using Cathflo Activase (alteplase) 2 mg to restore function to CVADs

INS

Infusion Nurses Society

The instillation of alteplase 2 mg (Cathflo Activase) is effective in restoring catheter patency in patients.²

—Class I; Level of Evidence A, *INS Infusion Therapy Standards of Practice, 2016, page S105, standard 48, practice criterion G*

Single-use vial

ONS

Oncology Nursing Society

Use 2 mg alteplase (Cathflo Activase) to restore patency and maintain catheter function.³

—Practice Standard, *ONS Access Device Standards of Practice, 2017, page 10, section VI, practice standard B*

AVA

Association for Vascular Access

“Alteplase (Cathflo Activase 2 mg) is the only FDA approved thrombolytic agent for the treatment of dysfunctional CVADs.”⁴

—AVA Study Guide, 2011, page 42, section F1-c

AACN

American Association of Critical-Care Nurses

“Declotting is done with 2 mg of tPA.”¹

—AACN Critical Care Nurse, 2007, volume 27, page 78

Use Cathflo Activase (alteplase) 2 mg as approved by the FDA

INS

Infusion Nurses Society

Instillation of tPA based on manufacturers' directions for use is recommended in current guidelines. There is limited research available to support the efficacy of thrombolytic drugs for alternative dosing.²

—Class I; Level of Evidence A, *INS Infusion Therapy Standards of Practice, 2016, page S105, standard 48, practice criterion G-2*

CDC

Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention (CDC) states that medications labeled as single dose or single use may only be used for one patient, for one single procedure.⁵

—CDC Guideline for Isolation Precautions, 2007, page 84, section IV.H.5

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.

CVAD=central venous access device (ie, nontunneled catheters, peripherally inserted central catheters, tunneled catheters, implanted ports).

Please see additional Important Safety Information on reverse side.

Cathflo Activase (alteplase) 2 mg is the standard of care for treatment of thrombotically occluded catheters

The Cathflo clinical trials were large trials with prespecified endpoints⁶

- In the pivotal trials COOL-1 and COOL-2, the efficacy of Cathflo 2 mg in 2 mL was evaluated in 1122 primarily adult patients

88%

Cumulative efficacy

In COOL-1, Cathflo restored function to 88% (112/127) of central lines after up to 2 doses using a 120-minute dwell time for each in catheters with occlusion present for up to 24 hours

74%

Maintained patency

In a subset of patients (n=346) in the COOL-1 and COOL-2 trials who had a successful treatment outcome, 74% (256/346) of central lines maintained patency up to 30 days after treatment with Cathflo

COOL=Cardiovascular Thrombolytic to Open Occluded Lines.

COOL-1—a double-blind, randomized, placebo-controlled study of 150 patients to evaluate the efficacy of Cathflo 2 mg/2 mL, in up to 2 doses, with function assessed at 120 minutes.

COOL-2—a phase III, single-arm, open-label, multicenter study of 995 patients to evaluate the safety of serial administration of up to 2 doses of Cathflo. Secondary objectives included assessing success rates at 30 minutes and 120 minutes.

Important Safety Information

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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.

Excessive pressure should be avoided when Cathflo Activase is instilled into the catheter. Such force could cause rupture of the catheter or expulsion of the clot into the circulation.

Bleeding

The most frequent adverse reaction associated with all thrombolytics in all approved indications is bleeding. Cathflo Activase has not been studied in patients known to be at risk for bleeding events that may be associated with the use of thrombolytics. Caution should be exercised with patients who have any condition for which bleeding constitutes a significant hazard.

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. Using Cathflo Activase in patients with infected catheters

may release a localized infection into the systemic circulation. As with all catheterization procedures, care should be used to maintain aseptic technique.

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.

Drug Interactions and Drug/Laboratory Test Interactions

The interaction of Cathflo Activase with other drugs has not been formally studied. Concomitant use of drugs affecting coagulation and/or platelet function has not been studied.

Potential interactions between Cathflo Activase and laboratory tests have not been studied.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate the carcinogenic potential or the effect on fertility.

Pregnancy

There are no adequate and well-controlled studies in pregnant women. Cathflo Activase should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Adverse Reactions

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

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

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

References: 1. Criddle LM. Ask the experts. *Crit Care Nurse*. 2007;27(3):78-81. 2. Infusion Nurses Society. Infusion therapy standards of practice. *J Infus Nurs*. 2016; 39(suppl 1):S1-S159. 3. Camp-Sorrell D, ed. *Access Device Standards of Practice for Oncology Nursing*. 4th ed. Pittsburgh, PA: Oncology Nursing Society; 2017:1-85. 4. AVA. Study Guide for Vascular Access Certification. Association for Vascular Access;2011:iii-164. 5. Siegel JD, Rhinehart E, Jackson M, Chiarello L, and the Healthcare Infection Control Practices Advisory Committee. 2007 Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings. <http://www.cdc.gov/hicpac/pdf/isolation/Isolation2007.pdf>. Accessed June 1, 2018. 6. Cathflo Prescribing Information. Genentech USA, Inc.

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