



May 28, 2024

Subject: Cathflo® Activase® (alteplase): Potential risk of impact on sterility of the product and voluntary recall of impacted batches in the US

Dear Health Care Provider:

The purpose of this letter is to inform you about the potential risk of impact on the sterility of Cathflo® Activase® (alteplase) and the voluntary recall of two batches of Cathflo® Activase® (alteplase) (batches 3618873 and 3618858).

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

During the filling of an unreleased batch of Cathflo, several defective stoppers were found jamming the stoppering line. Additional defective stoppers were found during visual inspection of the lyophilized vials. The scope of the ongoing investigation for deformed stoppers observed during filling operations for Cathflo® Activase® (alteplase) was expanded to include all drug product batches that used the same master lot of stoppers. Two of the drug product batches 3618873 and 3618858, that have been distributed to the US market are included in the scope of the investigation, as a stopper supplier defect cannot currently be excluded. A defective stopper may not seal properly resulting in a potential container closure integrity and sterility concern. Based on a 100% visual examination of the deformed stoppers the container closure integrity cannot be assured. Therefore, Roche/Genentech has decided to quarantine all impacted batches in scope of the ongoing investigation. Although there is currently no direct indication of a defect with these batches, Genentech is performing a Class 2 (may cause temporary or medically reversible adverse health consequences), Level 2 (distribution to the pharmacy/HCP), recall for the ~18,484 impacted units.

Serious Risks With Use of Cathflo® Activase® (alteplase)

Intravenous administration of a non-sterile drug can expose a patient to pathogens or opportunistic microorganisms which could result in serious infections ranging from fever, chills, and malaise, to severe adverse events such as septicemia, bacterial meningitides, and wound infection which may be life-threatening or even lead to a fatal outcome. Various factors influence the significance of the risk including the type of

contamination, pathogenicity, and virulence of the organisms in relation to the immunological state of the patients, and the total number of organisms present in the preparation ([Sargent, E. V. et. al. 2016. The regulatory framework for preventing cross-contamination of pharmaceutical products: History and considerations for the future. Regulatory Toxicology and Pharmacology, 79, S3-S10.](#))

Prescriber Action

- Cathflo® Activase® (alteplase) vials from batches 3618873 and 3618858 should not be used for any patient.
- Patients who have been treated with Cathflo® Activase® (alteplase) vials (batches 3618873 and 3618858) should be instructed to immediately report if they experience fever, chills, and/or malaise, which may be suggestive of an infection, to permit prompt and appropriate management.
- In case a patient experiences or reports adverse event(s) suspected to be associated with the use of Cathflo® Activase® (alteplase), healthcare providers should report such adverse events to Genentech at 1-888-835-2555

Reporting Adverse Events / Product Complaints and Company Contact

Health Care Providers should report any adverse events suspected to be associated with the use of Cathflo® Activase® (alteplase), to Genentech at 1-888-835-2555. Alternatively, this information may be reported to FDA's MedWatch reporting system by phone (1-800-FDA-1088) or online (www.fda.gov/medwatch).

Please report any product complaint suspected to be associated with the use of Cathflo® Activase® (alteplase), to Genentech at 1-800-334-0290.

Should you have any questions about the information in this letter or the safe and effective use of Cathflo® Activase® (alteplase), please feel free to contact us at: Genentech Medical Information/Communications Department at 1-800-821-8590.

If you have inventory of the impacted batches (3618873 and 3618858), call Qualanex at 1-877-881-8605 for recall instructions.

This letter is not intended as a complete description of the benefits and risks related to the use of Cathflo® Activase® (alteplase). Please refer to the enclosed [full prescribing information](#).

Sincerely,



Toby Patterson, MBBS
Senior Vice President
Head of U.S. Medical Affairs