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| **Manufacturer name:** | Genetech |
| **About the Recall:** | 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.<br><br>**Serious Risks With Use of Cathflo® Activase® (alteplase)**<br>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).* |
| **Products(s) numbers/models that are affected:** | Batches 3618873 and 3618858 |
| **URL Link(s) to Manufacturer Notice/Web Site:** | www.gene.com<br>1-800-334-0290 |

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| **Actions to be taken by customer/Patient:** | Discontinue use of any affected product. Patients who have been treated with these vials should immediately report of they experience fever, chills and/or malaise, which may suggest an infection. Any adverse effects suspected to be associated with the use of Cathflo Adivase (altepase), should be reported to Genetech. |