

INSTRUCTIONS FOR USE

Activase®

(alteplase) for injection

for intravenous use

100 mg (58 million IU)



Read before preparing Activase®

See also enclosed, full prescribing information
Instructions for Use should accompany
reconstituted Activase to patient bedside.

Kit Contents

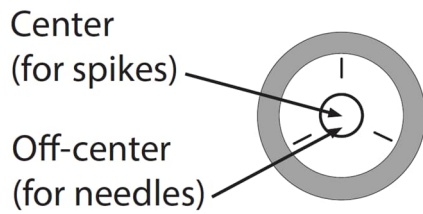
Transfer device



Activase vial
(no vacuum)



Activase vial stopper parts:



Sterile Water for Injection (water) vial

Note: Do not use Bacteriostatic Water for Injection, USP.



Prescribing Information

Instructions for Use

Also Required

(not included in kit)

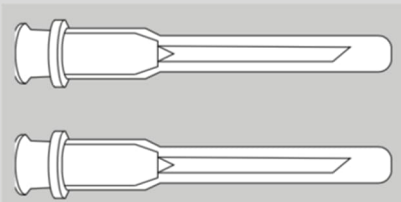
1 Luer syringe for removing bolus dose, as needed



1 Luer syringe for removing excess volume, as needed



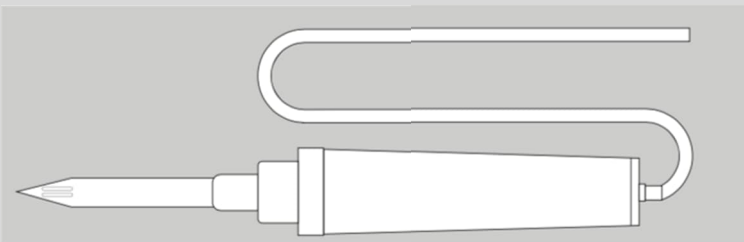
2 large bore needles



2 Alcohol swabs

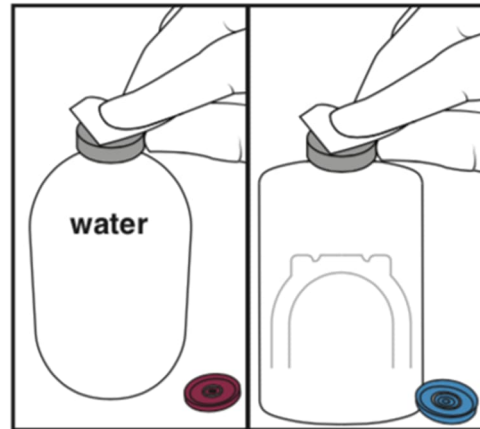


IV infusion set



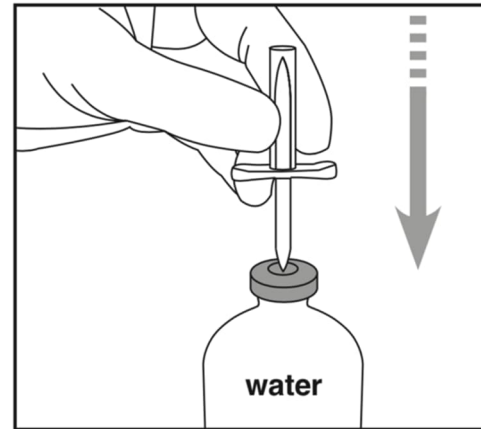
Reconstitution (use aseptic technique)

Step 1: Cleaning



- Remove caps from both vials.
- Wipe each stopper with a separate alcohol swab.

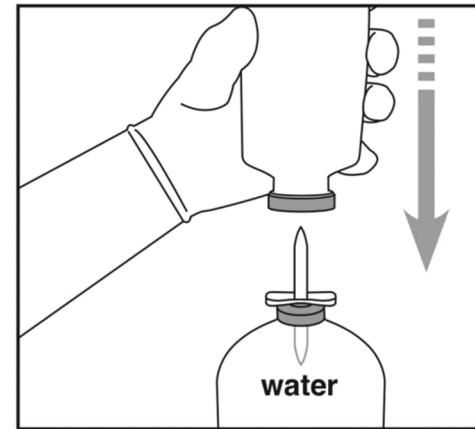
Step 2: Spiking Water vial



- Remove cover from one end of transfer device. **Do not wipe transfer device spikes with alcohol.** (Note: Either side of transfer device can be used.).
- Insert spike straight through center of water vial stopper.

! Do not invert water vial yet. Inverting too early may lead to leakage and incorrect dosing.

Step 3: Spiking Activase vial



- Remove cover from other end of transfer device.
- Hold Activase vial upside down over spike.
- Press Activase vial down to insert spike straight through center of Activase vial stopper.

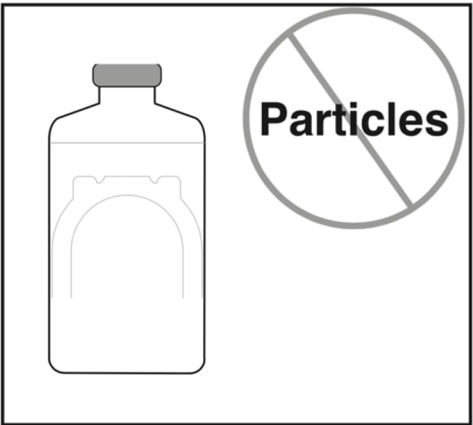
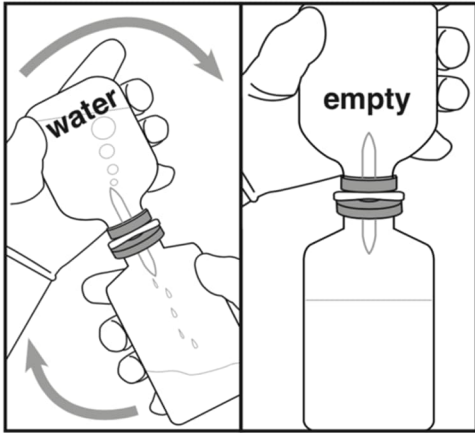
! Inserting the spike off-center could lead to stopper collapse.

Reconstitution (use aseptic technique)

Administration Warning

Step 4: Inverting and transferring

Step 5: Inspecting



- Invert vials so that water vial is on top.
- Allow all water to transfer into Activase vial.
- If the flow does not start immediately or pauses, initiate the flow by flipping and re-inverting the vials.
- Swirl gently and/or invert slowly to dissolve Activase powder.

Do not shake vials. Shaking may lead to excessive foaming and degraded medication.

- Separate empty water vial and transfer device from Activase vial.
- Reconstituted Activase vial (1 mg/mL) should be:
 - Colorless to pale yellow and transparent
 - Free of particulates
- If needed, let stand undisturbed for a few minutes to allow large bubbles to dissipate.



Review important information below before continuing to Step 6.

Do not push air from the syringe into the vial.

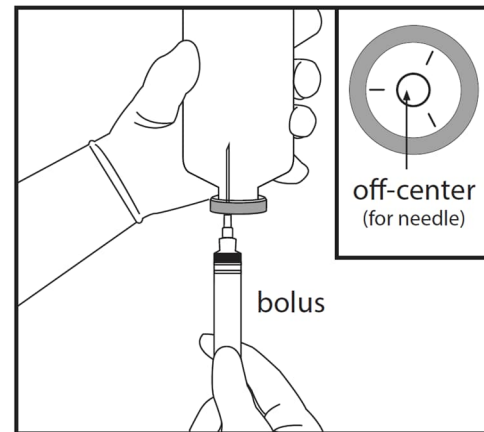
The vial is not under vacuum and adding air at any time may result in leakage and incorrect dosing.

Only insert needles within center ring of stopper, away from hole made by transfer device.

Insert needle within center ring of stopper, away from the hole made by transfer device when withdrawing medication to avoid leakage and incorrect dosing. Do not insert needles outside of the center ring of stopper.

Administration (use aseptic technique)

Step 6: Preparing bolus

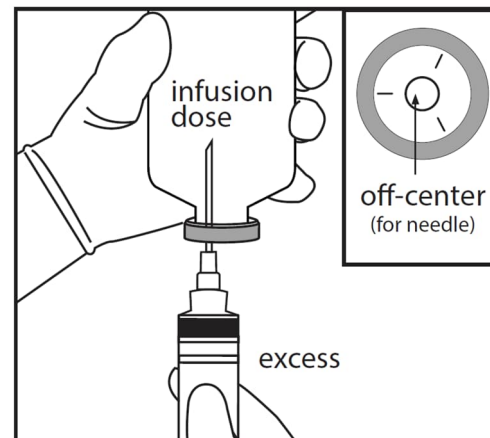


- Check if bolus is needed. If yes, attach needle to empty Luer syringe.
- Insert needle once through center ring of stopper, away from hole made by transfer device, and slowly withdraw the bolus amount.

! Do not push any air from syringe into vial (may cause leakage).

- Alternatively, the bolus can be left in the vial and administered via an infusion pump or removed from a port on the infusion line.

Step 7: Removing excess volume

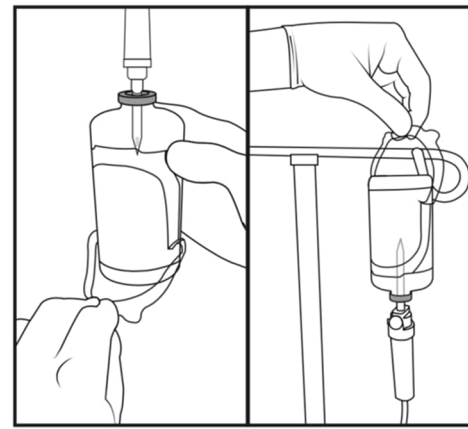


- Check if there is excess volume in vial. If yes, attach needle to empty Luer syringe.
- Insert needle once through center ring of stopper, away from hole made by transfer device, and slowly withdraw the excess volume.

! Do not push any air from syringe into vial (may cause leakage).

- Discard any excess volume.
- Leave infusion dose in vial.

Step 8: Spiking and hanging



- Insert spike from IV tubing set into center of vial stopper, through same hole made by transfer device.

! Do not make a new hole in the vial stopper. Additional holes in vial stopper may lead to leakage.

- Peel clear plastic hanger from vial label.
- Hang on IV pole and administer per facility protocol.

Administration Notes

- Activase is for intravenous administration only.
- Do not add any other medication to infusion solutions containing Activase.
- Extravasation of Activase infusion can cause ecchymosis or inflammation. If extravasation occurs, terminate the infusion at that IV site and apply local therapy.
- See full prescribing information for alternative dilution instructions.

Storage & Stability

- Store lyophilized Activase at controlled room temperature not to exceed 30°C (86°F), or under refrigeration at 2° to 8° C (36° to 46° F). Protect the lyophilized material during extended storage from excessive exposure to light.
- Activase contains no antibacterial preservatives and must be used within 8 hours following reconstitution (when stored at 2-30°C).

Manufactured by:
Genentech, Inc.
A Member of the Roche Group
1 DNA Way
South San Francisco, CA 94080-4990

U.S. License No. 1048

Activase® (alteplase) is a registered trademark of Genentech, Inc.

©2025 Genentech, Inc. All rights reserved.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Revised: February/2025