

## **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

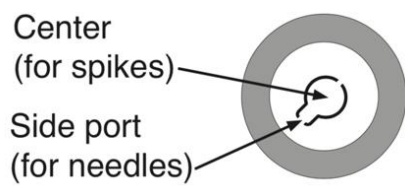
Transfer device



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)**

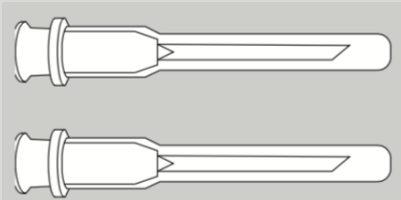
1 Luer syringe for removing bolus dose, as needed



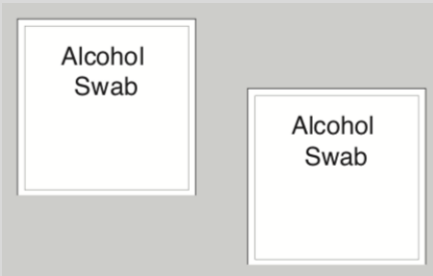
1 Luer syringe for removing excess volume, as needed



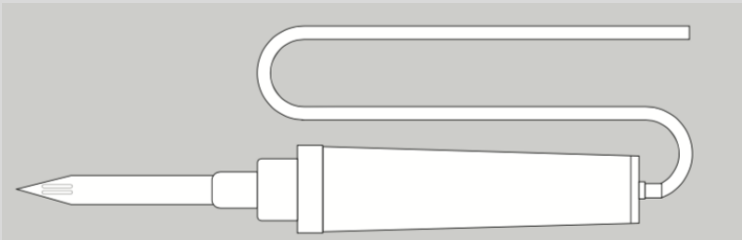
2 large bore needles



2 Alcohol swabs

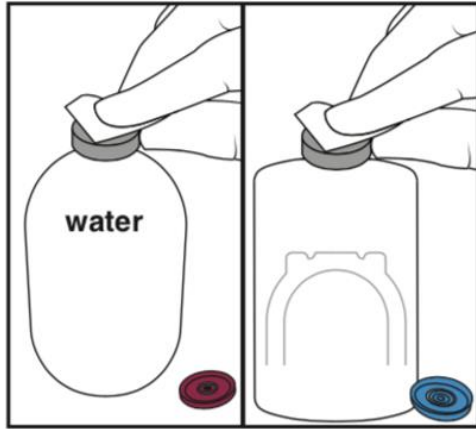


IV infusion set



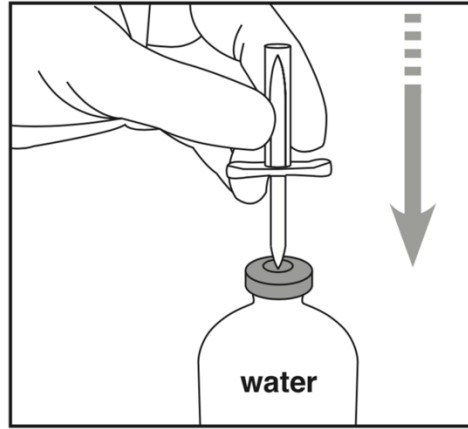
## Reconstitution (use aseptic technique)

### Step 1: Cleaning



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

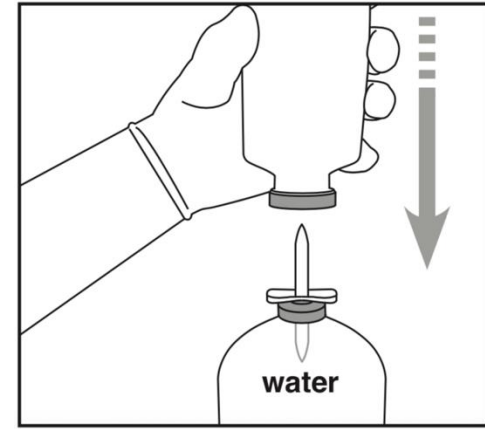
### Step 2: Spiking Water vial



- 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.

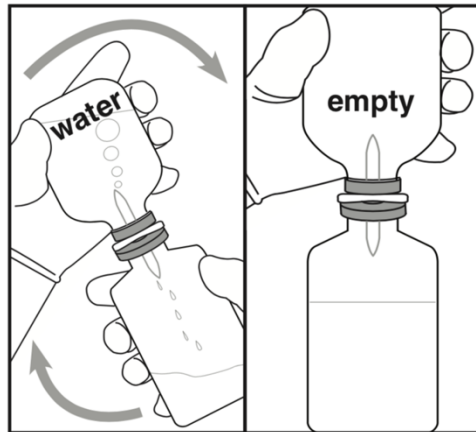
### Step 3: Spiking Activase vial



- 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.

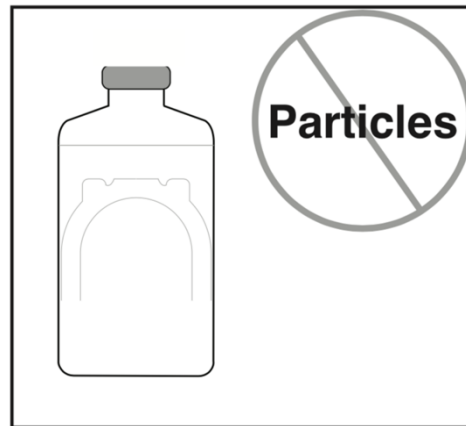
**Step 4: Inverting and transferring**



- 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.**

**Step 5: Inspecting**



- 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.**

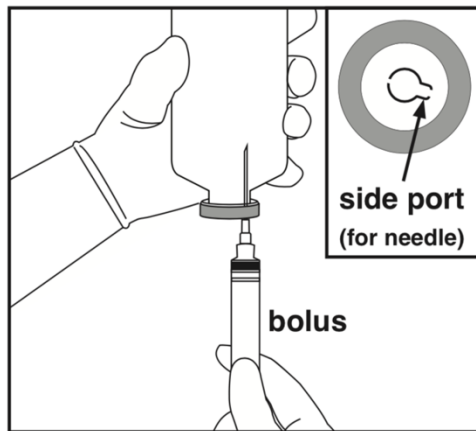
The vial is not under vacuum and adding air at any time may result in leakage and incorrect dosing.

**! Only insert needles into the side port.**

Insert needle into side port of vial stopper when withdrawing medication to avoid leakage and incorrect dosing. Do not insert needles into center of stopper.

## Administration (use aseptic technique)

### Step 6: Preparing bolus

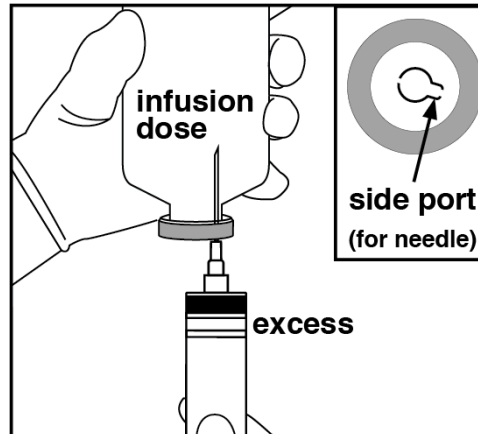


- Check if bolus is needed. If yes, attach needle to empty Luer syringe.
- Insert needle once through side port and slowly withdraw the bolus amount.

**! 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

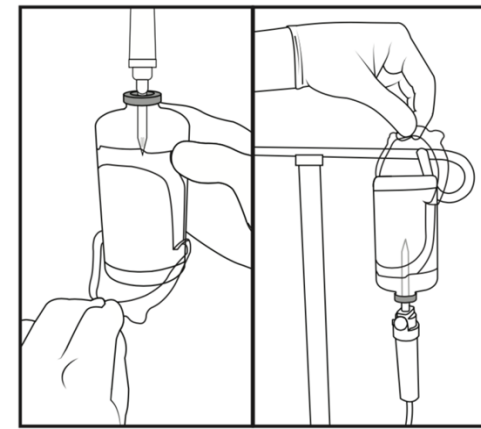


- Check if there is excess volume in vial. If yes, attach needle to empty Luer syringe.
- Insert needle once through side port and slowly withdraw the excess volume.

**! 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

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South San Francisco, CA 94080-4990

U.S. License No. 1048

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

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