INSTRUCTIONS FOR USE

Activase®
(alteplase) for injection
for intravenous use

100 mg (58 million IU)

STOP

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:

- Center (for spikes)
- Side port (for needles)

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).**

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°C to 8°C (36°F 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).