

Preparation of Activase Doses >50 mg Using Two 50 mg Vials (NDC 50242-0044-13)

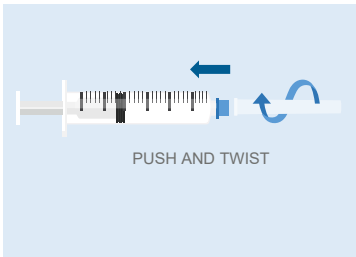
...

Reconstitution



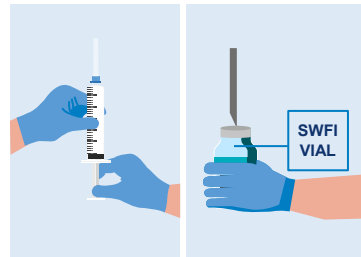
STEP 1

Remove protective caps from Activase vial and SWFI. Swab the top of each vial with an alcohol wipe to reduce the risk of contamination.



STEP 2

Place a large bore (e.g., 18 gauge) needle onto the 60-mL syringe.



STEP 3

Prime the syringe with air and pierce the SWFI vial stopper with the needle.



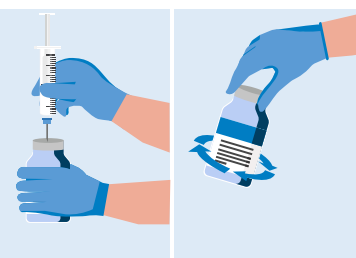
STEP 4

Withdraw 50 mL of SWFI.



STEP 5

After removing from the SWFI vial, insert needle into stopper of Activase 50 mg vial and inject all the contents directly into the lyophilized cake.



STEP 6

Remove the needle from the vial. Gently swirl the solution. **DO NOT SHAKE.** Slight foaming of the solution is normal. Let the solution stand undisturbed for several minutes to allow any large bubbles to dissipate.



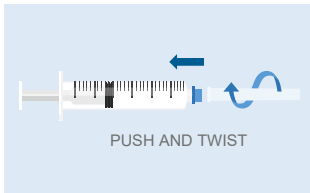
STEP 7

Repeat steps 2-6 with a new needle and new syringe for the second Activase 50 mg vial.

Acute Ischemic Stroke – Dose Preparation

Dosing: Determine weight-based dosing (0.9 mg/kg, not to exceed 90 mg total dose, with 10% of the total dose given as a bolus) (USPI section 2.1). To facilitate preparation, determine bolus dose, infusion dose, and discard quantity prior to reconstitution.

Bolus Dose



STEP 1

Attach a needle to a 10-mL syringe and prime the syringe with air.



STEP 2

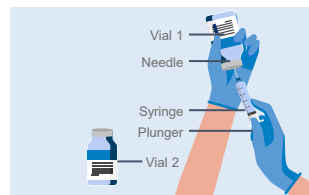
Pierce the center of the stopper of vial 1. Withdraw the appropriate bolus dose.

Infusion Dose



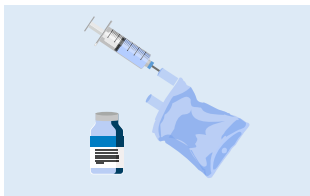
STEP 1

Using a new large syringe and needle, attach the needle to the syringe.



STEP 2

Withdraw the appropriate volumes from vials 1 and 2 for the infusion dose. Discard any excess medication.



STEP 3

Swab the port or stopper with an alcohol pad and inject the infusion volume into an empty polyvinyl chloride (PVC) bag or glass container.



STEP 4

Inspect the contents of the IV bag or glass container for particulates.

Acute Ischemic Stroke – Administration

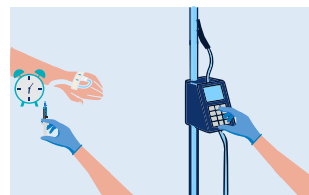
...

Infusing the Dose



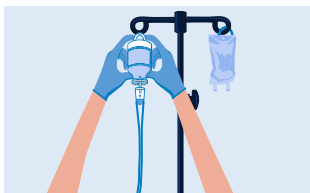
STEP 5

Hang IV bag or glass container and prime the line.



STEP 6

Administer the bolus dose via IV push or pump over 1 minute and then immediately start the infusion via pump or manually based on your institution's policy.



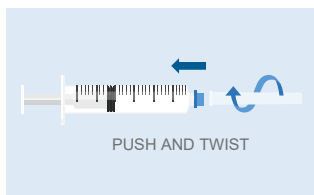
STEP 7

In accordance with hospital policy, clear the line at the end of the infusion (e.g., 100 mL of 0.9% sodium chloride at the same infusion rate as Activase) to ensure the entire Activase dose has been administered.

Acute Myocardial Infarction – Accelerated Infusion Dose Preparation and Administration

Dosing: Consult weight-based dosing charts and determine accelerated (Table 1 of USPI) or 3-hour (Table 2 of USPI) dosing regimen. To facilitate preparation, calculate bolus and infusion doses prior to reconstitution.

Bolus Dose for Accelerated Infusion



STEP 1

Attach a needle to a syringe and prime the syringe with air.



STEP 2

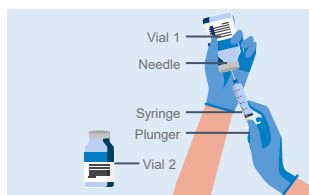
Pierce the center of the stopper of vial 1. Withdraw the appropriate bolus dose. Label the syringe.

Infusion Dose for Accelerated Infusion



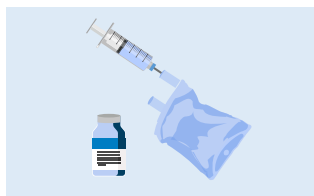
STEP 1

Using a new large syringe and needle, attach the needle to the syringe.



STEP 2

Withdraw the appropriate volumes from vials 1 and 2 in order to reach the “First 30 min” (Table 1 of USPI, Column 3) infusion dose.



STEP 3

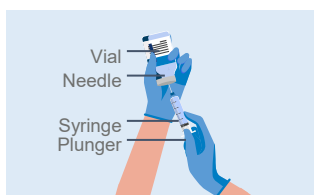
Swab the port or stopper with an alcohol pad and inject the “First 30 min” infusion volume into an empty PVC bag or glass container. Label the IV container.



STEP 4

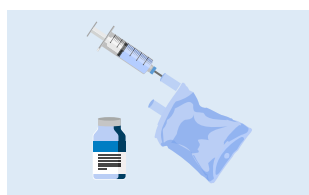
Inspect the contents of the IV bag or glass container for particulates.

Acute Myocardial Infarction – Accelerated Infusion



STEP 5

Using a new needle and syringe, draw up the infusion dose noted under “Next 60 min” (Table 1, column 4 in the USPI) from vial 2. Discard any excess medication.



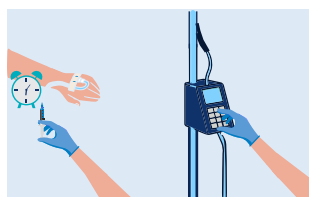
STEP 6

Swab the port or stopper with an alcohol pad and inject the “Next 60 min” infusion volume into an empty PVC bag or glass container. Label the IV container.



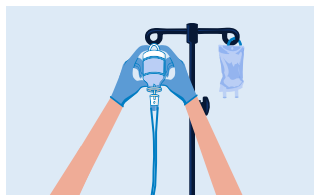
STEP 7

Inspect the contents of the IV bag or glass container for particulates.



STEP 8

Administer the bolus dose over 1 minute followed by the “First 30 min” infusion dose. Infuse for 30 min via pump or manually based on your institution’s policy. Immediately after, infuse the “Next 60 min” infusion dose over 1 hour.

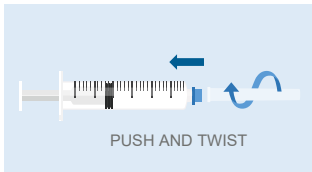


STEP 9

In accordance with hospital policy, clear the line at the end of the infusion (e.g., 100 mL of 0.9% sodium chloride) to ensure the entire Activase dose has been administered.

Acute Myocardial Infarction – 3-Hour Infusion Dose Preparation and Administration

Bolus Dose



STEP 1

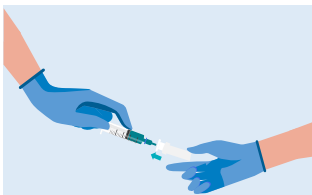
Attach a needle to a syringe and prime the syringe with air.



STEP 2

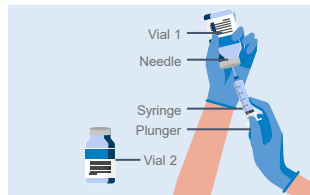
Pierce the center of the stopper of vial 1. Withdraw the appropriate bolus dose. Label the syringe.

Infusion Dose



STEP 1

Using a new large syringe and needle, attach the needle to the syringe.



STEP 2

Withdraw the appropriate volume from vials 1 and 2 in order to reach the "Rest of 1st hour" (Table 2 of USPI, Column 3) infusion dose.



STEP 3

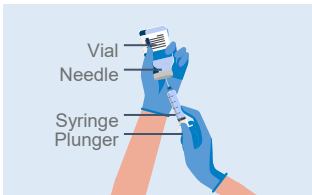
Swab the port or stopper with an alcohol pad and inject the "Rest of 1st hour" infusion volume into an empty PVC bag or glass container. Label the IV container.



STEP 4

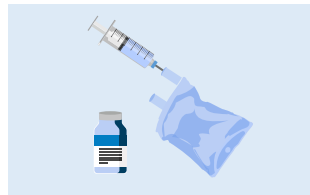
Inspect the contents of the IV bag or glass container for particulates.

Acute Myocardial Infarction – 3-Hour Infusion



STEP 5

Using a new needle and syringe, draw up the infusion dose noted under "2nd Hour" (Table 2, column 4 in the USPI) from vial 2.



STEP 6

Swab the port or stopper with an alcohol pad and inject the "2nd Hour" infusion volume into an empty PVC bag or glass container. Label the IV container.



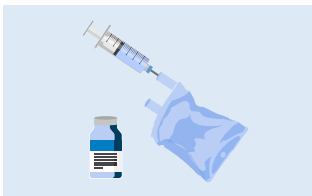
STEP 7

Inspect the contents of the IV bag or glass container for particulates.



STEP 8

Using another new needle and syringe, draw up the infusion dose noted under "3rd Hour" (Table 2, column 5 in the USPI) from vial 2.



STEP 9

Swab the port or stopper with an alcohol pad and inject the "3rd Hour" infusion volume into an empty PVC bag or glass container. Label the IV container.



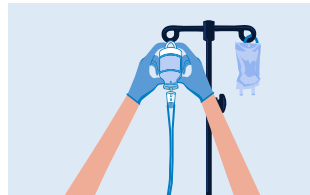
STEP 10

Inspect the contents of the IV bag or glass container for particulates.



STEP 11

Administer the bolus dose over 1 minute followed by the "Rest of 1st Hour" infusion dose. Infuse over the remaining first hour via pump or manually based on your institution's policy. Immediately after, infuse the "2nd Hour" and then the "3rd Hour" dose over Hour 2 and Hour 3, respectively.



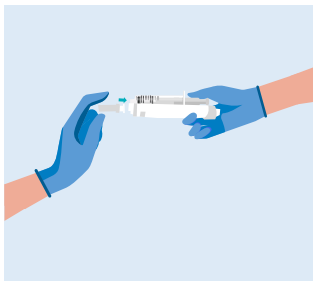
STEP 12

In accordance to hospital policy, clear the line at the end of the infusion (e.g., 100 mL of 0.9% sodium chloride at the same rate as the Activase infusion) to ensure the entire Activase dose has been administered.

Acute Massive Pulmonary Embolism – Dose Preparation and Administration

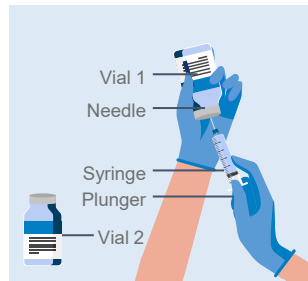
Dosing: Activase 100 mg administered by IV infusion over 2 hours (USPI Section 2.3)

Preparation



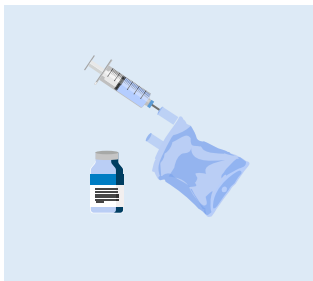
STEP 1

Using a new large syringe and needle, attach the needle to the syringe.



STEP 2

Withdraw the volume from vials 1 and 2 for the infusion dose.



STEP 3

Swab the port or stopper with an alcohol pad and inject the infusion volume into an empty PVC bag or glass container.

Administration



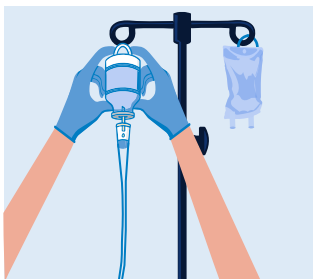
STEP 4

Inspect the contents of the IV bag or glass container for particulates.



STEP 5

Hang the bag and prime the line. Then infuse over 2 hours via pump or manually based on your institution's policy.



STEP 6

In accordance to hospital policy, clear the line at the end of the infusion (e.g., 100 mL of 0.9% sodium chloride at the same rate as the Activase infusion) to ensure the entire Activase dose has been administered.