INSTRUCTIONS FOR USE

ADZYNMA
(ad-zin-muh)
(ADAMTS13, recombinant-krhn)
Lyophilized Powder for Injection, for Intravenous Use
Single-Dose Vial
The following information is intended for medical or healthcare professionals only.

This Instructions for Use contains information on how to reconstitute and infuse **ADZYNMA**. This Instructions for Use is intended for the Healthcare Provider. Treatment with ADZYNMA should be prescribed and administered by a healthcare professional experienced in the treatment of blood disorders.

Important:
- **For intravenous injection after reconstitution only.**
- Use aseptic technique (clean and germ-free) throughout the procedure.
- Check the expiration date of the product prior to use.
- **Do not** use ADZYNMA if the expiration date has passed.

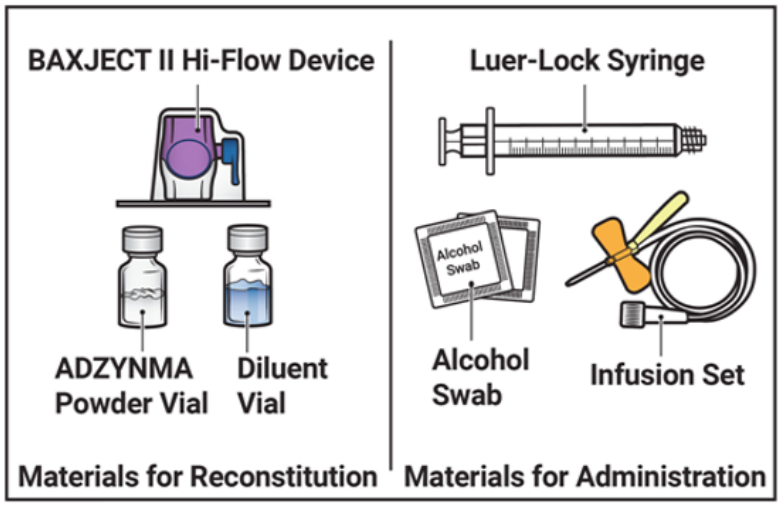
Storage of ADZYNMA

- Store ADZYNMA at refrigeration temperature of 36°F to 46°F [2°C to 8°C] until the expiration date stated on the carton.
- Can be stored at room temperature not to exceed 86°F/30°C for a period of 6 months, do not return to the refrigerator.
- **Do not** use beyond the expiration date printed on the carton or vial or if not stored properly.
- **Do not** freeze.
- Store vials in the original package to protect from light.

Reconstitution of ADZYNMA Using the BAXJECT II Hi-Flow Needleless Transfer Device

1. Prepare a clean, germ-free, flat surface and gather all the materials you will need for the reconstitution and infusion. **Figure A** depicts the materials provided in the carton box.

Figure A



2. **Do not** use ADZYNMA if the expiration date has passed.
    - Use ADZYNMA **within 3 hours** after reconstitution and keep at room temperature not to exceed 86°F/30°C. Do not store at any other temperature. Discard any unused reconstituted product if not used within 3 hours after reconstitution.
3. Allow the vials of ADZYNMA and diluent to reach room temperature before use.
    - If the patient needs more than one vial of ADZYNMA per injection, reconstitute each vial according to the instructions stated under “Reconstitution of ADZYNMA Using the BAXJECT II Hi-Flow Needleless Transfer Device”.
    - Inspect the reconstituted ADZYNMA solution for particulate matter and discoloration prior to administration. The solution should be clear and colorless in appearance.

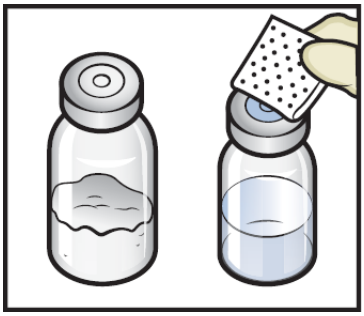
- **Do not** administer if particulate matter or discoloration is observed.

4. Wash and dry your hands thoroughly, and put on clean exam gloves.
5. Remove plastic caps from the ADZYNMA and diluent vials and place the vials on a flat surface (**Figure B**).

Figure B

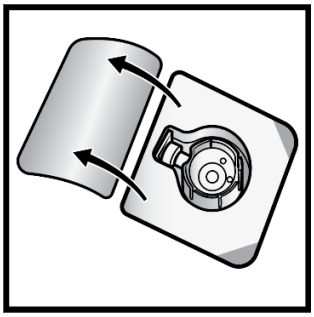
6. Wipe the rubber stoppers with an alcohol swab and allow them to dry prior to use. (**Figure C**).

Figure C



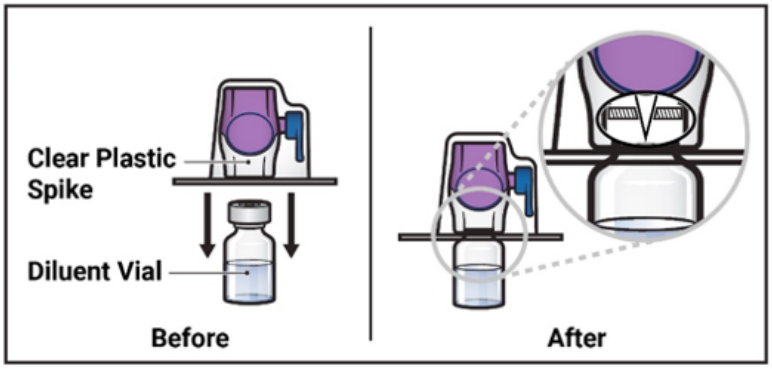
7. Open the BAXJECT II Hi-Flow device package by peeling away the lid, without touching the inside (**Figure D**).
   - **Do not** remove the BAXJECT II Hi-Flow device from the package.
   - **Do not** touch the **clear plastic spike**.

Figure D



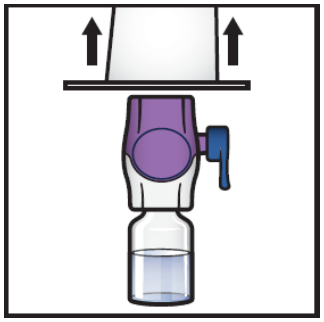
8. Turn the package with the BAXJECT II Hi-Flow device upside down and place it over the top of the diluent vial. Press straight down until the **clear plastic spike** pierces through the **diluent vial** stopper (**Figure E**).

Figure E



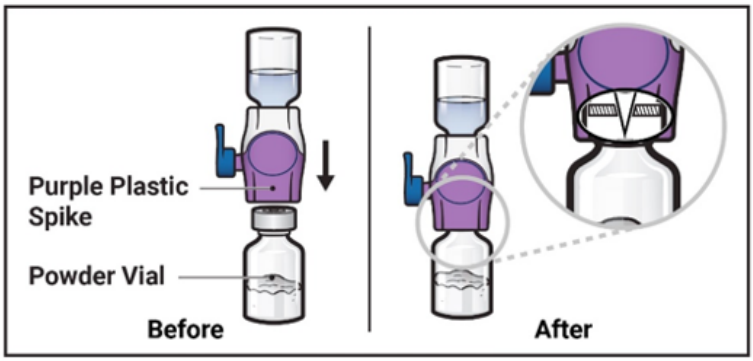
9. Grip the BAXJECT II Hi-Flow device package at its edge and pull the package off the device (**Figure F**).
    - **Do not** remove the **blue cap** from the BAXJECT II Hi-Flow device.
    - **Do not** touch the exposed **purple plastic spike**.

Figure F



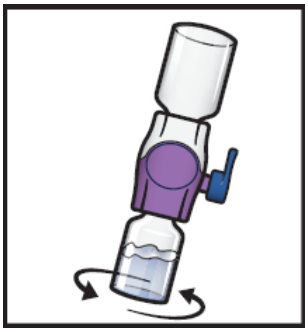
10. **Turn the system over** so that the **diluent vial** is now on top. Press the BAXJECT II Hi-Flow device straight down until the **purple plastic spike** pierces through the ADZYNMA **powder vial** stopper (**Figure G**). The vacuum will draw the diluent into the ADZYNMA **powder vial**.
    - You may notice some bubbles or foam – this is normal and should soon disappear. Wait until foam or bubbles dissipate before administration.

Figure G



11. Swirl the connected vials **gently** and continuously until the powder is completely dissolved (**Figure H**).
    - **Do not** shake the vial.

Figure H



12. Visually inspect the reconstituted solution for particulate matter before administration. The solution should be clear and colorless in appearance.
    - **Do not** use the product if particulate matter or discoloration is observed.
13. If the dose requires more than one vial of ADZYNMA, repeat step 1 to step 12 to reconstitute each vial.
    - **Use a different BAXJECT II Hi-Flow device to reconstitute each vial of ADZYNMA and diluent.**

Administration of ADZYNMA

14. Take off the **blue cap** from the BAXJECT II Hi-Flow device (**Figure I)**. Attach a Luer-lock syringe (**Figure J**).
    - **Do not** inject air into the system.

Figure I

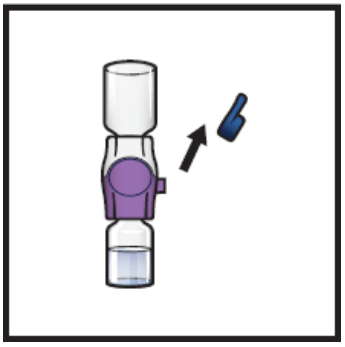
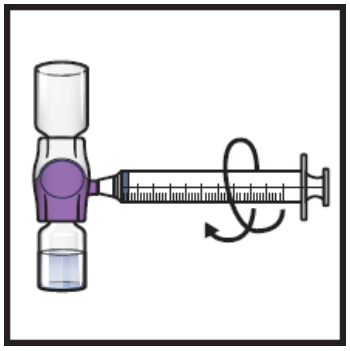
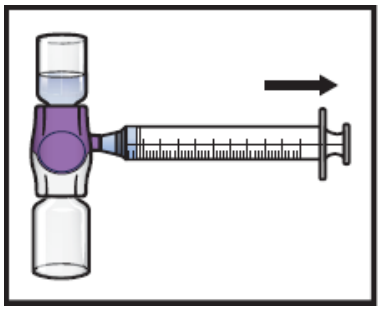


Figure J



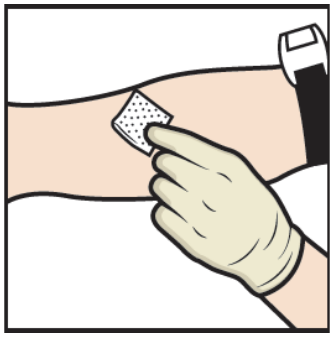
15. **Turn the system upside down** (ADZYNMA vial is now on top). Draw the **reconstituted solution** into the syringe by pulling the plunger back slowly (**Figure K**).
    - Use ADZYNMA **within 3 hours** after reconstitution and keep at room temperature (not to exceed 86°F/30°C). Do not store at any other temperature. Discard any unused reconstituted product if not used within 3 hours after reconstitution.
    - **Do not** administer ADZYNMA in the same tubing or container at the same time with other medicinal products for infusion.

Figure K



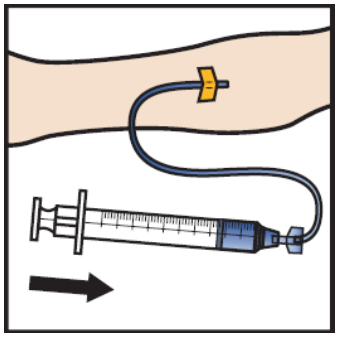
16. If a patient is to receive more than one vial of ADZYNMA, the contents of multiple vials can be drawn into the same syringe. Repeat this process for all reconstituted vials of ADZYNMA until the total volume to be administered is reached.
17. Disconnect the syringe and attach a suitable injection needle or an infusion set.
18. Point the needle up and remove any air bubbles by gently tapping the syringe with your finger and slowly and carefully pushing air out of the syringe and needle.
19. Apply a tourniquet and clean the chosen infusion site with an alcohol swab (**Figure L**).

Figure L



20. Insert the needle into the vein and remove the tourniquet.
21. Infuse the reconstituted ADZYNMA **slowly**, at a rate of **2 to 4 mL per minute** (**Figure M**).
    - A syringe pump may be used to control the rate of administration.

Figure M



22. Take the needle out of the vein, place a cotton ball or gauze on the infusion site, and apply pressure for several minutes to stop bleeding.
    - **Do not** recap the needle.
23. Place the needle, syringe, and empty vials in a puncture-resistant sharps container.
    - **Do not** dispose of syringes and needles in the regular waste.

Disposing of ADZYNMA

- Vials are for **single use** only. Any remaining solution in the vial must not be used and must be discarded in accordance with local requirements. Dispose used vials and other supplies in an FDA cleared sharps disposal container.
- **Do not** dispose of syringes and needles in the regular waste.

Manufactured by:
Takeda Pharmaceuticals U.S.A., Inc.
Lexington, MA 02421
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This Instructions for Use has been approved by the U.S. Food and Drug Administration.
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