

ADVATE® WITH BAXJECT III® RECONSTITUTION SYSTEM

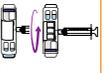
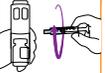
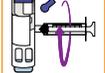
Do not attempt to do an infusion to yourself unless you have been taught how by your healthcare provider (HCP) or hemophilia center. For complete Instructions for Use, see the Instructions for Use section in the Prescribing Information.



[Antihemophilic Factor (Recombinant)]

IT'S ALL CONNECTED – SUMMARY OF INSTRUCTIONS FOR USE

If you require more than one vial of ADVATE with the BAXJECT III RECONSTITUTION system, follow the reconstitution steps below and draw the contents of each system into the same large syringe when reconstitution is complete.

<p>STEP 1: Prepare a clean flat surface and gather all the materials you will need for the infusion. Check the expiration date, and let the ADVATE warm up to room temperature. Wash your hands and put on clean exam gloves. If infusing yourself at home, the use of gloves is optional.</p> 	<p>STEP 6: Take off the blue cap from the housing and connect the syringe. Be careful not to inject air into the ADVATE.</p> 	<p>STEP 11: Take the needle out of the vein and use sterile gauze to put pressure on the infusion site for several minutes.</p> 
<p>STEP 2: Open the ADVATE package by peeling away the lid. Remove the ADVATE from the package and visually inspect the contents of the product and diluent vial. The ADVATE powder should be white to off-white in color and the diluent should not contain particles. Do not use if discoloration or particles are seen.</p> 	<p>STEP 7: Turn over the ADVATE so that the vial containing the ADVATE solution is on top. Draw the ADVATE solution into the syringe by pulling back the plunger slowly. If the solution does not draw into the syringe, be sure that both vials are pressed firmly together. The contents of more than one vial may be drawn into a single, appropriately sized syringe if you are using more than one vial of ADVATE.</p> 	<p>STEP 12: Do not recap the needle. Place the needle, syringe, and ADVATE in a hard-walled sharps container for proper disposal. Do not dispose of these supplies in ordinary household trash.</p> 
<p>STEP 3: Place on a flat surface with the diluent vial on top. The diluent vial has a blue stripe.</p> 	<p>STEP 8: Disconnect the syringe from the system. Attach the infusion needle to the syringe using a winged (butterfly) infusion set, if available. 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.</p> 	<p>STEP 13: Remove the peel-off label from the housing and place it in your logbook. Clean any spilled blood with a freshly prepared mixture of 1 part bleach and 9 parts water, soap and water, or any household disinfecting solution.</p> 
<p>STEP 4: With one hand holding the ADVATE housing, press down firmly on the diluent vial with the other hand until the system is fully collapsed and the diluent flows down into the ADVATE vial. Both vials will move into the housing when pressed. If you don't see the diluent transfer to the product vial, press the vials again to assure they are completely inserted. <u>Do not remove the blue cap</u> until instructed in a later step.</p> 	<p>STEP 9: Apply a tourniquet and get the injection site ready by wiping the skin well with an alcohol swab (or other suitable solution suggested by your healthcare provider or hemophilia center).</p> 	<p>IMPORTANT: <u>Contact your healthcare provider or local hemophilia treatment center if you experience any problems.</u></p>
<p>STEP 5: Swirl the ADVATE gently and continuously until the ADVATE is completely dissolved. <u>Do not shake. Do not refrigerate after reconstitution.</u> Inspect the ADVATE solution for particulate matter and discoloration prior to administration. The solution should be clear and colorless in appearance. If not, do not use the solution and notify your healthcare provider immediately.</p> 	<p>STEP 10: Insert the needle into the vein and remove the tourniquet. Slowly infuse the ADVATE. <u>Do not infuse any faster than 10 mL per minute.</u></p> 	<p> Do not shake. Do not refrigerate after reconstitution. Solution must be used within 3 hours of reconstitution.</p>

ADVATE [Antihemophilic Factor (Recombinant)] Important Information

What is ADVATE?

- ADVATE is a medicine used to replace clotting factor (factor VIII or antihemophilic factor) that is missing in people with hemophilia A (also called "classic" hemophilia).
- ADVATE is used to prevent and control bleeding in adults and children (0-16 years) with hemophilia A. Your healthcare provider (HCP) may give you ADVATE when you have surgery.
- ADVATE can reduce the number of bleeding episodes in adults and children (0-16 years) when used regularly (prophylaxis).

ADVATE is not used to treat von Willebrand disease.

DETAILED IMPORTANT RISK INFORMATION

Who should not use ADVATE?

- Do not use ADVATE if you:
- Are allergic to mice or hamsters.
 - Are allergic to any ingredients in ADVATE.

Tell your HCP if you are pregnant or breastfeeding because ADVATE may not be right for you.

Reference: 1. ADVATE Prescribing Information.

Please see ADVATE Detailed Important Risk Information continued on page 2.

For additional important safety information, click here for [Prescribing Information](#) and discuss with your HCP.



TROUBLESHOOTING GUIDE

The following instructions will guide you through recovering ADVATE® if the initial reconstitution procedure does not work. Some steps may need to be repeated from this initial reconstitution procedure.

Reasons why there might be a diluent transfer difficulty:

- If you activated the ADVATE with BAXJECT III® RECONSTITUTION system upside down (vial with blue stripe at bottom)
- If the system is tilted or tipped on its side while diluent is transferring
- If the blue cap located on the side of the system is removed before activating the system
- If you have injected air into the system in error
- If you did not press down hard enough to activate or fully seat both vials inside their respective housing



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 <p>STEP 1: Position the ADVATE with BAXJECT III RECONSTITUTION system with the water vial on top. The water vial has the blue stripe.</p>	 <p>STEP 5: Connect syringe to the system. Do not overtighten. <u>Do not inject air into the system.</u></p>	 <p>STEP 9: Reconnect the syringe to the ADVATE with BAXJECT III RECONSTITUTION system.</p>
 <p>STEP 2: Make sure the product and water vials are pressed into their respective housing as far as possible by pressing down with only one hand while holding the system vertically on a flat surface with another hand.</p>	 <p>STEP 6: Keep water vial with blue stripe up, and pull the syringe plunger back slowly. This draws air from the vials and pulls water down in to the ADVATE vial. Stop pulling the plunger when almost all water flows down to ADVATE vial. It is normal for some water (less than 0.4 mL) to remain in the water vial.</p>	 <p>STEP 10: Turn the system over so that the vial with the ADVATE solution is on top (vial with blue stripe at bottom).</p>
 <p>STEP 3: Remove the blue cap located on the side of the reconstitution system.</p>	 <p>STEP 7: Unscrew the syringe from the system. Again, press the plunger all the way down to expel any air from the syringe.</p>	 <p>STEP 11: Slowly pull the plunger back to withdraw the mixed ADVATE into the syringe. The system may be rocked back and forth or from side to side to withdraw as much mixed product as possible.</p>
 <p>STEP 4: Press the plunger on the syringe all the way down to expel any air from the syringe.</p>	 <p>STEP 8: Swirl ADVATE with BAXJECT III RECONSTITUTION system gently and continuously until the ADVATE is completely dissolved.</p>	 <p>STEP 12: Disconnect the syringe from the system. You are now ready to infuse (no faster than 10 mL per minute over a period of ≥ 5 minutes).</p>

If these steps fail to address the problems you are having, please contact your healthcare provider or local hemophilia treatment center.

What should I tell my HCP before using ADVATE?

Tell your HCP if you:

- Have or have had any medical problems.
- Take any medicines, including prescription and non-prescription medicines, such as over-the-counter medicines, supplements or herbal remedies.
- Have any allergies, including allergies to mice or hamsters.
- Are breastfeeding. It is not known if ADVATE passes into your milk and if it can harm your baby.
- Are or become pregnant. It is not known if ADVATE may harm your unborn baby.
- Have been told that you have inhibitors to factor VIII (because ADVATE may not work for you).

What important information do I need to know about ADVATE?

- You can have an allergic reaction to ADVATE. Call your HCP right away and stop treatment if you get a rash or hives, itching, tightness of the throat, chest pain or tightness, difficulty breathing, lightheadedness, dizziness, nausea or fainting.
- Do not attempt to infuse yourself with ADVATE unless you have been taught by your HCP or hemophilia center.

What else should I know about ADVATE and Hemophilia A?

- Your body may form inhibitors to factor VIII. An inhibitor is part of the body's normal defense system. If you form inhibitors, it may stop ADVATE from working properly. Talk with your HCP to make sure you are carefully monitored with blood tests for the development of inhibitors to factor VIII.

What are possible side effects of ADVATE?

- Side effects that have been reported with ADVATE include: cough, headache, joint swelling/aching, sore throat, fever, itching, unusual taste, dizziness, hematoma, abdominal pain, hot flashes, swelling of legs, diarrhea, chills, runny nose/congestion, nausea/vomiting, sweating, and rash. Tell your HCP about any side effects that bother you or do not go away or if your bleeding does not stop after taking ADVATE.

You are encouraged to report negative side effects of prescription drugs to the FDA. For additional safety information, click here for [Prescribing Information](#) and discuss with your HCP.

Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

To view the BAXJECT III Reconstitution Demonstration and Troubleshooting Guide videos,

visit: <https://www.advate.com/dosing/baxject-iii-system.html>