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.

**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.

### ADVATE [Antihemophilic Factor (Recombinant)]

**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.

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

**DETAILED IMPORTANT RISK INFORMATION**

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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**STEP 1:**
Position the ADVATE with BAXJECT III RECONSTITUTION system with the water vial on top. The water vial has the blue stripe.

**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.

**STEP 3:**
Remove the blue cap located on the side of the reconstitution system.

**STEP 4:**
Press the plunger on the syringe all the way down to expel any air from the syringe.

**STEP 5:**
Connect syringe to the system. Do not overtighten. Do not inject air into the system.

**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 into the ADVATE vial. It is normal for some water (less than 0.4 mL) to remain in the water vial.

**STEP 7:**
Unscrew the syringe from the system. Again, press the plunger all the way down to expel any air from the syringe.

**STEP 8:**
Swirl ADVATE with BAXJECT III RECONSTITUTION system gently and continuously until the ADVATE is completely dissolved.

**STEP 9:**
Reconnect the syringe to the ADVATE with BAXJECT III RECONSTITUTION system.

**STEP 10:**
Turn the system over so that the vial with the ADVATE solution is on top (vial with blue stripe at bottom).

**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.

**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).

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

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**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 is 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.

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**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, hemorrhoma, 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.

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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

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