

Baxter, ADVATE – Antihemophilic Factor (Recombinant)

ADVATE, Recombinant Antihemophilic Factor, is indicated for the prevention and control of bleeding episodes in people with hemophilia A (classical hemophilia).

ADVATE is also indicated for perioperative management of patients with hemophilia A.

ADVATE is the first and only factor VIII therapy made without the addition of human or animal blood-derived components.

ADVATE is available in several different potencies, including a super-high potency format (1500 IU/vial), and it has a small infusion volume (5mL diluent), meaning patients can administer their therapy conveniently and quickly. In addition, while ADVATE should be refrigerated it also has the advantage of being stored for up to six months at room temperature, or up to the expiration date, whichever ever comes first. It is packaged with a 10mL syringe, butterfly needle and BAXJECT a needleless reconstitution device.

Contraindications to the use of Advate:

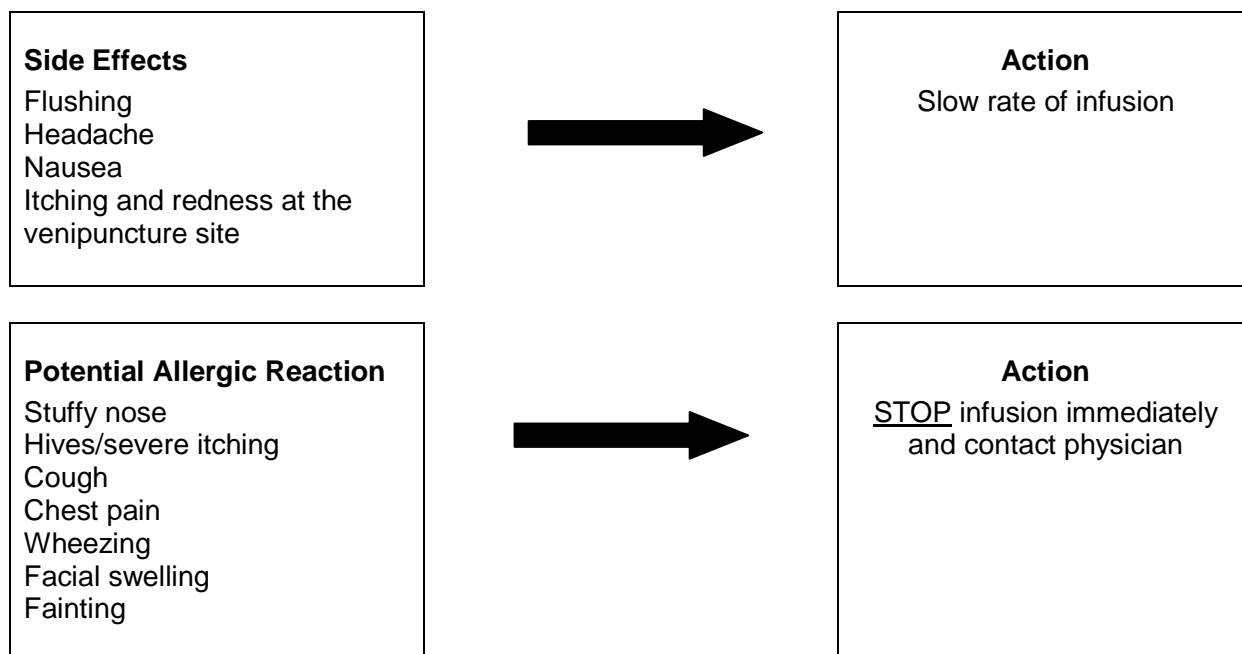
Known hypersensitivity to mouse or hamster proteins

Known intolerance or allergic reaction to any of the constituents in the formulation of Advate

Side Effects:

The most common related adverse reactions observed during the ADVATE clinical studies, include strange taste in mouth, headache, dizziness and flushing.

Management of Adverse Effects:



Product monograph available at:

http://www.advate.com/pdf/advate_pi.pdf

BAXTER: ADVATE (Recombinant FVIII)



STEP 1

Bring ADVATE to room temperature (NOT >37°C) before using.

Choose a clean, dry, well-lit work area and lay out the following supplies:

Contained in Smaller Box

- Bottle(s) of factor VIII powder- check dose & expiry date
- Bottle (s) of sterile water
- BAXJECT II device (s)

Contained in Larger Box

- 1 10 ml sterile syringe
- 1 butterfly infusion set (#23 gauge)
- 2 adhesive bandages

Packaged Separately

- (2) Alcohol swabs



STEP 2

Wash hands

- Use warm running water
- Use antibacterial soap from pump dispenser
- Dry hands with a paper towel
- Turn off taps with paper towel & discard



STEP 3

Remove the caps from the bottle(s) of FVIII powder and sterile water.



STEP 4

Clean the tops of the bottles with an alcohol swab. Allow to dry completely. **DO NOT** blow on the tops to speed up drying, this will contaminate them. Place the vials on a flat surface.

STEP 5



Open the BAXJECT II device package by peeling away the lid without touching the inside of the package.

DO NOT REMOVE DEVICE FROM PACKAGE.



STEP 6

Turn the package with the device upside down over the top of the bottle of sterile water (white side up). Press down the clear plastic spike of the BAXJECT II device into the center of the bottle of sterile water. Grip the package at its edge and pull it off the device.

DO NOT REMOVE BLUE CAP. DO NOT TOUCH WHITE SPIKE



STEP 7

Quickly invert device with the water vial attached to the BAXJECT II device (white side down) and place on top of the bottle containing the factor, press down until the white spike pierces through the center of the rubber stopper. The vacuum will draw the sterile water into the bottle of factor.



STEP 8

Swirl gently to dissolve the product.

IT IS ACCEPTABLE FOR A SMALL AMOUNT OF WATER TO BE LEFT BEHIND. IF THE WATER DOES NOT TRANSFER SUCCESSFULLY, PLEASE REFER TO THE TROUBLESHOOTING GUIDE.

STOP HERE:

Go to Step 13 if prescribed dose requires more than one vial.



STEP 9

Remove the blue cap from the BAXJECT II device. Connect the syringe to the BAXJECT II device.

DO NOT INJECT AIR.



STEP 10

Turn the system over so that the bottle with the factor solution is on top. Withdraw all the factor solution by pulling slowly on the plunger.

IF YOU FIND IT IMPOSSIBLE TO WITHDRAW SOME OR ALL OF THE MIXED PRODUCT INTO THE SYRINGE, THERE MAY BE AIR IN THE DEVICE. PLEASE REFER TO THE TROUBLESHOOTING GUIDE.



Peripheral Vein

STEP 11

Disconnect the syringe leaving the BAXJECT II device connected. Attach the butterfly needle for peripheral vein infusion. Holding the syringe and the needle pointing up, gently flick the syringe to move any air bubbles to the top and gently push on the plunger to remove the air. **DO NOT** push any factor solution out of the syringe.



Port

STEP 12

Attach a blunt cannula for PORT infusion Mark the syringe with a piece of tape if using PORT.

MULTIVIAL DOSE

STEP 13

Mix all product vials, using a new BAXJECT II device for each vial, as directed in Step 1 – 8 to prepare the prescribed dose to the nearest vial. Select a syringe large enough to hold the prescribed dose.



STEP 14

Follow Step 9 – 10 to draw the product from each vial into the larger syringe. **DO NOT INJECT AIR.** Go to Step 10 for administration using a butterfly infusion set or Step 11 for administration through an established peripheral IV or Port-a-Cath®.



Administer the dose of ADVATE by bolus infusion over a period of < 5 minutes (maximum infusion rate, 10 mL/min).

See http://www.lhsc.on.ca/sworhp/nursing_guidelines.htm for “Troubleshooting Information”