




ADYNOVATE
[Antihemophilic Factor
(Recombinant), PEGylated]

HEMOPHILIA A
IS A PIECE OF YOU.
NOT ALL OF YOU.

No actual patients depicted.

ADYNOVATE® With BAXJECT III® Instructions for Use

ADYNOVATE Important Information

What is ADYNOVATE?

- ADYNOVATE is an injectable medicine that is used to help treat and control bleeding in children and adults with hemophilia A (congenital Factor VIII deficiency).
- Your healthcare provider (HCP) may give you ADYNOVATE when you have surgery.
- ADYNOVATE can reduce the number of bleeding episodes when used regularly (prophylaxis).

ADYNOVATE is not used to treat von Willebrand disease.

SELECTED IMPORTANT RISK INFORMATION

Who should not use ADYNOVATE?

Do not use ADYNOVATE if you:

- Are allergic to mice or hamster protein
- Are allergic to any ingredients in ADYNOVATE or ADVATE® [Antihemophilic Factor (Recombinant)]

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

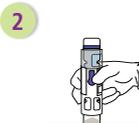
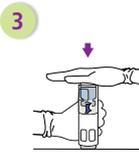
Please see ADYNOVATE Detailed Important Risk Information throughout.
[Click here for Full Prescribing Information.](#)

ADYNOVATE 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. Always follow the specific instructions given by your healthcare provider. The steps listed below are general guidelines for using ADYNOVATE. If you are unsure of the procedures, please call your healthcare provider before using. Call your healthcare provider right away if bleeding is not controlled after using ADYNOVATE. Your healthcare provider will prescribe the dose that you should take.

IMPORTANT: Contact your healthcare provider or local hemophilia treatment center if you experience any problems.

Press

-  Prepare a clean flat surface and gather all the materials you will need for the infusion.
 - Check the expiration date, and let the ADYNOVATE 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
-  Open the ADYNOVATE package by peeling away the lid. Remove the ADYNOVATE from the package and visually inspect the contents of the product and diluent vial. The ADYNOVATE 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.
-  Place on a flat surface with the diluent vial on top. The diluent vial has a blue stripe. With 1 hand holding the ADYNOVATE 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 ADYNOVATE 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. **Do not remove the blue cap** until instructed in a later step.

ADYNOVATE Important Information

What is ADYNOVATE?

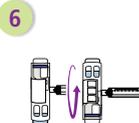
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ADYNOVATE is not used to treat von Willebrand disease.

Swirl

-  Swirl the ADYNOVATE gently and continuously until the ADYNOVATE is completely dissolved. **Do not shake. Do not refrigerate after reconstitution.** Inspect the ADYNOVATE 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.

DO NOT shake. DO NOT refrigerate after reconstitution. Solution must be used within 3 hours of reconstitution.

-  Take off the blue cap from the housing and connect the syringe. Be careful to not inject air into the ADYNOVATE.
-  Turn over the ADYNOVATE so that the vial containing the ADYNOVATE solution is on top. Draw the ADYNOVATE 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 1 vial may be drawn into a single, appropriately sized syringe if you are using more than 1 vial of ADYNOVATE.

DETAILED IMPORTANT RISK INFORMATION

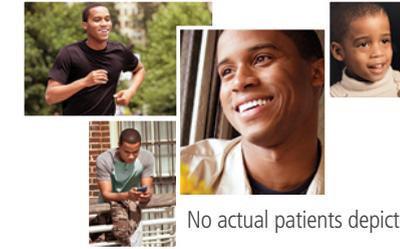
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Summary of Instructions for Use

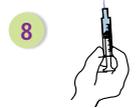
For complete Instructions for Use, please see the ADYNOVATE Prescribing Information [here](#).



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Flip & Withdraw

-  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.
-  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).
-  Insert the needle into the vein and remove the tourniquet. Slowly infuse the ADYNOVATE. **Do not infuse any faster than 10 mL per minute.**
-  Take the needle out of the vein and use sterile gauze to put pressure on the infusion site for several minutes.
-  Remove the peel-off label from the blister lid 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.
-  Do not recap the needle. Place the needle, syringe, and ADYNOVATE system in a hard-walled Sharps container for proper disposal. Do not dispose of these supplies in ordinary household trash.

If you require more than 1 reconstitution system, follow the steps above and draw the contents of each system into the same large syringe when reconstitution is complete.

DETAILED IMPORTANT RISK INFORMATION (continued)

What should I tell my HCP before using ADYNOVATE?

- 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 ADYNOVATE passes into your milk and if it can harm your baby.
 - Are or become pregnant. It is not known if ADYNOVATE may harm your unborn baby.
 - Have been told that you have inhibitors to factor VIII (because ADYNOVATE may not work for you).

DETAILED IMPORTANT RISK INFORMATION (continued)

What important information do I need to know about ADYNOVATE?

- You can have an allergic reaction to ADYNOVATE. Call your healthcare provider 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 ADYNOVATE unless you have been taught by your HCP or hemophilia center.

Please see ADYNOVATE Detailed Important Risk Information continued on the next page.

[Click here for Full Prescribing Information.](#)

TROUBLESHOOTING GUIDE

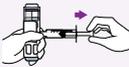
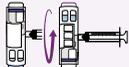
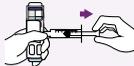
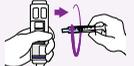
The following instructions will guide you through recovering ADYNOVATE if the initial reconstitution procedure does not work. Some steps may need to be repeated from this initial reconstitution procedure.


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Reasons why there might be a diluent transfer difficulty:

- If you activated the ADYNOVATE 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

RECOVERY PROCEDURE

 <p>1 Position the ADYNOVATE with BAXJECT III Reconstitution System with the water vial on top. The water vial has the blue stripe.</p>	 <p>5 Connect the syringe to the system. Do not overtighten. Do not inject air into the system.</p>	 <p>9 Reconnect the syringe to the ADYNOVATE with BAXJECT III Reconstitution System.</p>
 <p>2 Make sure the product and water vials are pressed into their respective housing as far as possible by pressing down with only 1 hand while holding the system vertically on a flat surface with another hand.</p>	 <p>6 Keep the water vial with the blue stripe up, and pull the syringe plunger back slowly. This draws air from the vials and pulls water down into the ADYNOVATE vial. Stop pulling the plunger when almost all water flows down to the ADYNOVATE vial. It is normal for some water (less than 0.4 mL) to remain in the water vial.</p>	 <p>10 Turn the system over so that the vial with the ADYNOVATE solution is on top (vial with blue stripe at bottom).</p>
 <p>3 Remove the blue cap located on the side of the Reconstitution System.</p>	 <p>7 Unscrew the syringe from the system. Again, press the plunger all the way down to expel any air from the syringe.</p>	 <p>11 Slowly pull the plunger back to withdraw the mixed ADYNOVATE 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>4 Press the plunger on the syringe all the way down to expel any air from the syringe.</p>	 <p>8 Swirl the ADYNOVATE with BAXJECT III Reconstitution System gently and continuously until the ADYNOVATE is completely dissolved.</p>	 <p>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 HCP or local hemophilia treatment center.

DETAILED IMPORTANT RISK INFORMATION (continued)

What else should I know about ADYNOVATE 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 ADYNOVATE 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 ADYNOVATE?

- The common side effects of ADYNOVATE are headache and nausea. These are not all the possible side effects with ADYNOVATE. Tell your HCP about any side effects that bother you or do not go away.

You are encouraged to report negative side effects of prescription drugs to the FDA.

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

[Click here for Full Prescribing Information.](#)

REFERENCE: 1. ADYNOVATE Prescribing Information.