



Healthcare Provider Discussion Guide

A guide to help start the conversation with your healthcare provider (HCP) to see if ADYNOVATE® [Antihemophilic Factor (Recombinant), PEGylated] is right for you

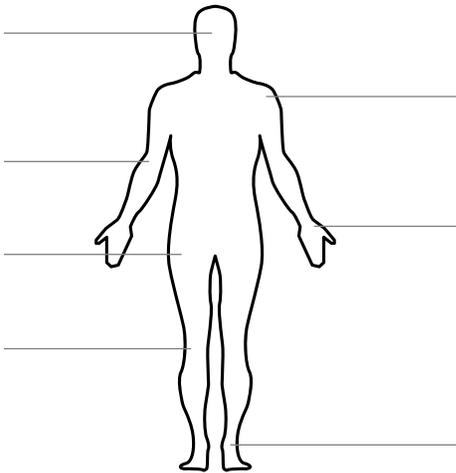
Prepare for your next visit

Tracking bleeds, setting goals, and answering the following questions can help you determine your treatment needs before visiting your healthcare provider. Fill out and print this guide to bring with you to your next appointment.

 How many bleeds did I experience in the past year?

_____ bleeds

 Where on my body did my bleeds occur? (Check all that apply.)



 Do I have recurring bleeds in any of my joints?

 What is my realistic bleed rate goal?

_____ bleeds per year

 Does my current dosing schedule fit my lifestyle? If not, how would I change it?

 Have I missed any infusions in the past year? If so, why?

 Do I have any medical, surgical, or dental procedures coming up?

 What physical activity do I participate in and how often?

Please see page 3 for ADYNOVATE Detailed Important Risk Information. For additional safety information, click here for [Full Prescribing Information](#), and see page 4 for Important Facts about ADYNOVATE and discuss with your HCP.

myPKFiT® for Patients Mobile Application is Rx only. For safe and proper use of the myPKFiT Mobile App, please refer to the complete instructions for use in the User Manual.

ADYNOVATE is a prescription injectable medicine used to prevent and control bleeding in adults and children with congenital hemophilia A.


ADYNOVATE
[Antihemophilic Factor
(Recombinant), PEGylated]



Ask your healthcare provider about ADYNOVATE®

Everyone has their own unique needs when it comes to treatment. Asking the right questions can help you and your healthcare provider find a regimen that works for you.

 What's a realistic bleed rate goal I should be striving for? What is considered well controlled?

 How can ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated] help me reach my bleed-reduction goals?

 What are the risks and possible side effects of ADYNOVATE?

 How do I know if ADYNOVATE is an appropriate treatment choice for me? Can its dosing schedule fit my lifestyle?

 How can ADYNOVATE dosing be personalized to fit my lifestyle?

 What is myPKFiT® mobile app?

 How can ADYNOVATE treatment be personalized using myPKFiT?

Additional questions and notes

Please see page 3 for ADYNOVATE Detailed Important Risk Information. For additional safety information, click here for [Full Prescribing Information](#), and see page 4 for Important Facts about ADYNOVATE and discuss with your HCP.

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ADYNOVATE
[Antihemophilic Factor
(Recombinant), PEGylated]



IMPORTANT INFORMATION

What is ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated] and ADVATE® [Antihemophilic Factor (Recombinant)]?

- ADYNOVATE and ADVATE are each prescription, injectable medicines that are used to replace clotting factor, to help treat and control bleeding in children and adults with hemophilia A (congenital Factor VIII deficiency, also called “classic” hemophilia).
- Your healthcare provider (HCP) may give you ADYNOVATE or ADVATE when you have surgery.
- ADYNOVATE and ADVATE can each reduce the number of bleeding episodes when used regularly (prophylaxis).

ADYNOVATE and ADVATE are not used to treat von Willebrand disease.

DETAILED IMPORTANT RISK INFORMATION

Who should not use ADYNOVATE and ADVATE?

Do not use ADYNOVATE or ADVATE if you:

- Are allergic to mouse or hamster proteins.
- Are allergic to any ingredients in ADYNOVATE or ADVATE.

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

What should I tell my HCP before using ADYNOVATE and 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 hamster proteins.
- Are breastfeeding. It is not known if ADYNOVATE or ADVATE pass into your milk or if they can harm your baby.
- Are or become pregnant. It is not known if ADYNOVATE or ADVATE may harm your unborn baby.
- Have been told that you have inhibitors to factor VIII (because ADYNOVATE or ADVATE may not work for you).

What important information do I need to know about ADYNOVATE and ADVATE?

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

What else should I know about ADYNOVATE, 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 ADYNOVATE or 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 ADYNOVATE and ADVATE?

- **ADYNOVATE:** The common side effects of ADYNOVATE are headache, diarrhea, rash, nausea, dizziness, and hives. 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.
- **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. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

For additional safety information, click here for [Full Prescribing Information](#), and see page 4 for Important Facts about ADYNOVATE and discuss with your HCP.

myPKFiT® FOR ADYNOVATE PATIENTS MOBILE APPLICATION INTENDED USE

- The myPKFiT for Patients Mobile Application (“myPKFiT Mobile App”) is intended for use by patients with hemophilia A being treated with ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated] who are 12 years of age or older with a body weight of 29 kg or higher and their caregivers.
- The myPKFiT Mobile App is designed to make it convenient for you to record your infusion and bleed events, track your estimated Factor VIII levels following a prophylactic infusion, and export the data for review by your health care provider (“HCP”).
- Your HCP can use the myPKFiT software to generate ADYNOVATE dosage amount and frequency recommendations for routine prophylaxis using your age, body weight information, and laboratory tests that measure your Factor VIII clotting activity. Using myPKFiT software, HCPs can evaluate various prophylaxis dose regimens tailored to your individual needs and treatment plan.
- myPKFiT Mobile App should only be used by hemophilia A patients treated with ADYNOVATE, as per the ADYNOVATE Prescribing Information.
- myPKFiT Mobile App is not indicated for use by patients with von Willebrand disease. myPKFiT Mobile App should not be used by patients who have developed inhibitors to Factor VIII products.

myPKFiT for Patients Mobile Application is Rx only. For safe and proper use of the myPKFiT Mobile App, please refer to the complete instructions for use in the User Manual.



ADYNOVATE
[Antihemophilic Factor
(Recombinant), PEGylated]

Patient Important Facts about

ADYNOVATE® [Antihemophilic Factor (Recombinant), PEGylated]

This leaflet summarizes important information about ADYNOVATE. Please read it carefully before using this medicine. This information does not take the place of talking with your healthcare provider, and it does not include all of the important information about ADYNOVATE. If you have any questions after reading this, ask your healthcare provider.

What is the most important information I need to know about ADYNOVATE?

Do not attempt to do an infusion to yourself unless you have been taught how by your healthcare provider or hemophilia center.

You must carefully follow your healthcare provider's instructions regarding the dose and schedule for infusing ADYNOVATE so that your treatment will work best for you.

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 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.

Who should not use ADYNOVATE?

You should 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 healthcare provider if you are pregnant or breastfeeding because ADYNOVATE may not be right for you.

How should I use ADYNOVATE?

ADYNOVATE is given directly into the bloodstream.

You may infuse ADYNOVATE at a hemophilia treatment center, at your healthcare provider's office or in your home. You should be trained on how to do infusions by your healthcare provider or hemophilia treatment center. Many people with hemophilia A learn to infuse their ADYNOVATE by themselves or with the help of a family member.

Your healthcare provider will tell you how much ADYNOVATE to use based on your individual weight, level of physical activity, the severity of your hemophilia A, and where you are bleeding.

Reconstituted product (after mixing dry product with wet diluent) must be used within 3 hours and cannot be stored or refrigerated. Discard any ADYNOVATE left in the vial at the end of your infusion as directed by your healthcare professional.

You may have to have blood tests done after getting ADYNOVATE to be sure that your blood level of factor VIII is high enough to clot your blood.

How should I use ADYNOVATE? (cont'd)

Call your healthcare provider right away if your bleeding does not stop after taking ADYNOVATE.

What should I tell my healthcare provider before I use ADYNOVATE?

You should tell your healthcare provider 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 pregnant or planning to 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).

What are the possible side effects of 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.

The common side effects of ADYNOVATE are headache, diarrhea, rash, nausea, dizziness, and hives. Tell your healthcare provider about any side effects that bother you or do not go away.

These are not all the possible side effects with ADYNOVATE. You can ask your healthcare provider for information that is written for healthcare professionals.

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. Consult with your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to Factor VIII.

Medicines are sometimes prescribed for purposes other than those listed here. Do not use ADYNOVATE for a condition for which it is not prescribed. Do not share ADYNOVATE with other people, even if they have the same symptoms that you have.

The risk information provided here is not comprehensive.

To learn more, talk with your health care provider or pharmacist about ADYNOVATE. The FDA-approved product labeling can be found at www.ADYNOVATE.com or 1-877-TAKEDA-7.

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.

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