UNLOCKING YOUR PATIENTS' SELF-POTENTIAL

Please see page XX for ADVATE Detailed Important Risk Information. Please see enclosed ADVATE full Prescribing Information.

ADVATE
[Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method]

A key to living fully

www.advate.com | 888.4.ADVATE

Baxter

ADVATE is the only recombinant FVIII that is FDA approved for prophylaxis in both adults & children (0-16 years)[1]

UNLOCKING YOUR PATIENTS' SELF-POTENTIAL

Hemophilia patients want more out of life today. They aspire to achieve a sense of freedom and independence.

ADVATE, with its prophylaxis treatment regimens, established clinical reputation, and convenience options,[1] supports your patients as they strive to live life more fully and unlock their self-potential.

Indication for ADVATE

ADVATE [Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method] is indicated for control and prevention of bleeding episodes in adults and children (0-16 years) with hemophilia A and for the perioperative management in adults and children (0-16 years) with hemophilia A.

ADVATE is indicated in routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children (0-16 years) with hemophilia A.

ADVATE is not indicated for the treatment of von Willebrand Disease.

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HELPING PATIENTS LIVE LIFE MORE FULLY

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The Four Keys to ADVATE:

1. PERFORMANCE

Prophylaxis Results[1]

Significant bleed reduction and improved physical health–related quality of life compared to on-demand

2. PROVEN

Proven Profile of Clinical Performance[2-8]

Well-documented, proven results

3. PERSONALIZED

Customized Treatment Options Built on Choice and Convenience[1]

A broad range of options to customize and personalize treatment

4. DEDICATED

Advancements in Treatment and the Baxter Difference

Baxter's ongoing commitment to the hemophilia community

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Selected Important Risk Information for ADVATE

ADVATE is contraindicated in patients with known anaphylaxis to mouse or hamster protein or other constituents of the product.

The serious adverse reactions seen with ADVATE are hypersensitivity reactions and the development of high-titer inhibitors necessitating alternative treatments to factor VIII.

The most common adverse reactions observed in clinical trials (frequency ≥10% of subjects) were pyrexia, headache, cough, nasopharyngitis, vomiting, arthralgia, and limb injury.

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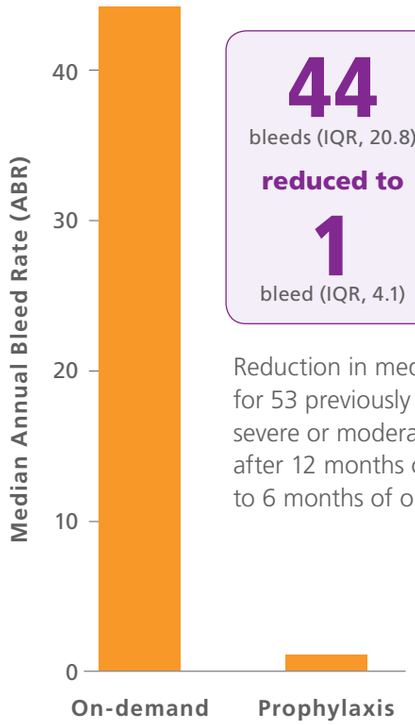
Significant Reduction in Annual Bleed Rate (ABR) Compared to On-demand Treatment[1]

On-demand vs prophylaxis



44 bleeds (IQR, 20.8)

reduced to

1 bleed (IQR, 4.1)

98% **reduction** in bleeds when switched to prophylaxis

Reduction in median annual bleed rate for 53 previously treated patients with severe or moderately severe hemophilia A after 12 months of prophylaxis, compared to 6 months of on-demand.[1,a]

Median ABR of 1 after switching to prophylaxis (IQR, 4.1)[1]

42% of patients experienced zero bleeds during 1 year on prophylaxis[1]

No subject developed FVIII inhibitors or withdrew due to an adverse event (AE)[2]

[a]A multicenter, open-label, randomized, 2-arm, prospective phase IV clinical study evaluated the relative efficacy of ADVATE in 2 prophylactic regimens—every second day (standard) prophylaxis dosed at 20-40 IU/kg every 48 hours and every third day (pharmacokinetic-driven) prophylaxis dosed at 20-80 IU/kg every 72 hours, targeted to maintain FVIII trough levels ≥1%.

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Proven Profile of Clinical Performance

- **9 years of real-world experience[11]**
- **More than 12 billion IUs distributed worldwide[12]**
- **Extensively studied rFVIII treatment[2-8]**
- **Proven record of efficacy and safety[2-8]**

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Reduced Frequency Dosing (Every Third Day)

Infusion calendar schedules

60 POTENTIAL FEWER INFUSIONS PER YEAR

Sun	Mon	Tues	Wed	Thurs	Fri	Sat
X		X		X		X
	X		X		X	
X		X		X		X
	X		X		X	

Standard Dosing
(every second day prophylaxis)

Sun	Mon	Tues	Wed	Thurs	Fri	Sat
	X			X		
X			X			X
		X			X	
	X			X		

Reduced Frequency Dosing
(every third day prophylaxis)

X X INFUSION DAYS

INFUSION-FREE DAYS

Help your patients see what a difference a Reduced Frequency Dosing schedule can make.

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Every Package of ADVATE Contains BAXJECT II Needle-less Transfer Device

BAXJECT II needle-less transfer device for safe, fast, and easy mixing

BAXJECT II Product Information

Rx Only. For safe and proper use of this device, please refer to the instructions for use.

The BAXJECT II device is intended for use with a single vial of product and is for single use only. Therefore, reconstitution and withdrawing a second vial into the syringe requires a second BAXJECT II device.

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Selected Important Risk Information for ADVATE

Allergic-type hypersensitivity reactions, including anaphylaxis, are possible and have been reported with ADVATE. Symptoms have manifested as dizziness, paresthesias, rash, flushing, face swelling, urticaria, dyspnea, and pruritus. Discontinue use if hypersensitivity symptoms occur and administer appropriate emergency treatment.

Carefully monitor patients treated with AHF products for the development of factor VIII inhibitors by appropriate clinical observations and laboratory tests. Inhibitors have been reported following administration of ADVATE predominantly in previously untreated patients (PUPs) and previously minimally treated patients (MTPs).

The maximum infusion rate is 10 mL/min.

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ADVATE Offers a Broad Selection of Doses, Providing Opportunities for Single-Vial Options[1]

2 mL
Sterile Water for Injection (diluent)

5 mL
Sterile Water for Injection (diluent)

ADVATE: Customized convenience with 2 mL diluent volume

- Convenience: 60% reduction of infusion volume[1]
- Flexibility: 7 different potencies available with a 2 mL diluent volume, up to 1700 IU
- Simplicity: Same easy reconstitution procedures with BAXJECT II device
- Proven bioequivalence to ADVATE reconstituted in 5 mL diluent volume[1,a]

[a]From an open-label, randomized, crossover study comparing pharmacokinetics and safety.

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