Patients may be eligible to receive 6 free trial doses of ADVATE®



Fax Document to: 1-866-467-7740

INSTRUCTIONS:

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- 1. Review Program Terms and confirm Eligibility criteria below.
- 2. Healthcare prescriber and patient to complete the enrollment form.
- 3. Healthcare prescriber and patient to sign the authorization and release. If patient is unable to sign this form prior to submission, Takeda will contact patient to obtain signature.
- 4. Fax completed form to Takeda at [1-866-467-7740].
- 5. Takeda will contact healthcare prescriber or patient to coordinate shipment of trial doses.

Patient Name			Gender M F
Date of Birth (MM/DD/YYYY)			I certify I am new to ADVATE
Address			Apt/Unit #
City	State	ZIP	Telephone
E-mail			Primary Language
Patient Guardian Name (if applicable)			
Address			Apt/Unit #
City	State	ZIP	Telephone
E-mail			Primary Language

PATIENT AUTHORIZATION AND RELEASE

If patient is unable to sign this form prior to submission, Takeda will contact patient to obtain signature.

I authorize any health plan, physician, healthcare professional, hospital, clinic, pharmacy provider, or other healthcare provider (collectively, "Providers") to disclose my (or Patient's) protected health information, including personal information relating to my medical condition, treatment, care management, and health insurance, as well as all information provided on this form and any prescription ("Information"), to Takeda Pharmaceutical Company Limited ("Takeda"). I understand Takeda may provide this Information to its affiliates and their representatives, agents, and contractors, as well as to a specialty pharmacy, for the purpose of facilitating my (or Patient's) participation in the Freedom of Choice free trial program. This Information may also be used for internal uses by Takeda, including data analysis.

Patient Signature	_ Date
Patient Guardian Signature (if applicable)	_ Date

PATIENT CONSENT FOR FUTURE INFORMATION (OPTIONAL)

□ By checking this box, I authorize the use of my Information for Takeda marketing activities and consent to receiving marketing and promotional communications from Takeda. I hereby give consent to Takeda, its affiliates, and their agents and representatives to send communications and information to me via the contact information I have provided to Takeda. I understand that this consent will be in effect until such time as I cancel such authorization.

Please see page 4 for ADVATE Detailed Important Risk Information. Please <u>click here</u> for ADVATE full Prescribing Information.



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SHIPPING

Ship to Prescriber's office Patient's home (no PO boxes) When shipping to prescriber's office, product(s) must be addressed to prescriber. Complete this section only if the shipping address differs from the one provided in the "Patient" or "Prescriber" section.

Name	Address		Apt/	/Unit #
City	State	ZIP	Telephone	
E-mail				

The shipment will include 6 doses of ADVATE. Each dose of ADVATE is packaged with Sterile Water for Injection (sWFI), one BAXJECT III® reconstitution device, one full prescribing physician insert, and one patient insert.

The following sections must be completed by the prescriber. Be sure to print all information, and sign before submitting.

Prescriber Name	Specialty					
Facility or Prescriber's Tax ID #	NPI #					
Institution Name	Office Contact					
Office Address	Unit #					
City	State ZIP					
Direct Office Telephone I	E-mail					
ICD-10 Diagnosis Code						
Severity of Hemophilia A: Mild Moderate Severe Patient's Current Hemophilia A Treatment						
Your Takeda Representative						
Please fill out the prescription information below for ADVATE to be provided as a part of this FREEDOM OF CHOICE program. Ensure all dosing requirements are included.						
Patient Name						
Address	Date of Birth (MM/DD/YYYY)					
Any Known Allergies						
Patient Weight(kg)						
ADVATE Dosage: Total IUs Required for One Dose (pharmacy will dete	ermine vial potency to fulfill six [6] doses)					

PRESCRIBER AUTHORIZATION AND RELEASE (REQUIRED)

By signing this form, I certify that therapy with ADVATE is medically necessary for the patient identified in this enrollment form ("Patient"). I have reviewed the current ADVATE Prescribing Information and will be supervising Patient's treatment. I have received from Patient, or his/her personal representative, the necessary authorization to release, in accordance with applicable federal and state law regulations, referenced medical and/or other patient information relating to ADVATE therapy to Takeda Pharmaceutical Company Limited, including its agents, representatives, or contractors (collectively, "Takeda"), and to the specialty pharmacy, for the purposes of enrolling the patient in the Freedom of Choice free trial program ("Program").

I certify that free trial product provided through the Program will not be exported or transferred in exchange for money, other property, or services. I further certify that no portion of the free trial will be used for reimbursement purposes, including from Medicare, Medicaid, or any third-party program that provides cost- or charge-based reimbursement to the participating institution, either directly or indirectly.

Prescriber Signature

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Date

For more information, call Takeda at 1-888-229-8379.

Please see page 4 for ADVATE Detailed Important Risk Information. Please <u>click here</u> for ADVATE full Prescribing Information.



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PROGRAM TERMS AND ELIGIBILITY

To be eligible, patients must have a valid prescription and a confirmed diagnosis of hemophilia A.

TERMS AND CONDITIONS:

- 1. This free trial offer is solely intended to allow new patients to try ADVATE[®] [Antihemophilic Factor (Recombinant)], and to determine with their healthcare provider whether ADVATE is right for them. There is no obligation to continue use of ADVATE after the free trial has been completed.
- 2. This free trial prescription is valid for one time only with no refills. For any future use, the patient must obtain a new prescription for ADVATE.
- 3. Free trial of ADVATE may only be delivered to the patient's home or to the prescriber's address listed on this enrollment form (no PO boxes).
- 4. Free trial of ADVATE cannot be exported or transferred in exchange for money, other property, or services.
- 5. No portion of this free trial may be submitted for reimbursement to any third-party payer, including Medicare or Medicaid, either directly or indirectly.
- 6. This program is valid only for residents of the United States.
- 7. Takeda reserves the right to change or discontinue this program at any time without notice.
- 8. This is not a financial assistance or cost-savings program.
- 9. Initiation of this free trial program requires certain processing time. It is not intended to provide Factor product(s) to address an active or ongoing bleed at the time of enrollment.



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ADVATE [ANTIHEMOPHILIC FACTOR (RECOMBINANT)] IMPORTANT INFORMATION

Indications

ADVATE is a recombinant antihemophilic factor indicated for use in children and adults with hemophilia A (congenital factor VIII deficiency) for:

- Control and prevention of bleeding episodes
- Perioperative management
- Routine prophylaxis to prevent or reduce the frequency of bleeding episodes

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

Detailed Important Risk Information

CONTRAINDICATIONS

Patients who have life-threatening hypersensitivity reactions, including anaphylaxis, to mouse or hamster protein or other constituents of the product.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Allergic-type hypersensitivity reactions, including anaphylaxis, have been reported with ADVATE. Symptoms include dizziness, paresthesia, rash, flushing, facial swelling, urticaria, dyspnea, pruritus, and vomiting. Discontinue ADVATE if hypersensitivity symptoms occur and administer appropriate emergency treatment.

Neutralizing Antibodies

Neutralizing antibodies (inhibitors) have been reported following administration of ADVATE predominantly in previously untreated patients (PUPs) and previously minimally treated patients (MTPs). Monitor all patients for the development of factor VIII inhibitors by appropriate clinical observation and laboratory testing. If expected plasma factor VIII activity levels are not attained, or if bleeding is not controlled with an expected dose, perform an assay that measures factor VIII inhibitor concentration.

ADVERSE REACTIONS

- Serious adverse reactions seen with ADVATE are hypersensitivity reactions, including anaphylaxis, and the development of high-titer inhibitors necessitating alternative treatments to factor VIII.
- The most common adverse reactions observed in clinical trials (>5% of subjects) were pyrexia, headache, cough, nasopharyngitis, arthralgia, vomiting, upper respiratory tract infection, limb injury, nasal congestion, and diarrhea.

Please click here for ADVATE full Prescribing Information.

