ADVATE
[Antihemophilic Factor (Recombinant)]

FREEDOM OF CHOICE™

ADVATE® TRIAL PROGRAM ENROLLMENT FORM

Instructions

1. Review Program Terms and Eligibility criteria.
2. Complete the enrollment form with your healthcare provider.
3. Ensure your healthcare provider reviews and signs the certification, authorization, and release.
4. Fax completed form to **1-866-467-7740**
5. Prescription will be filled and shipped via overnight courier directly to the designated address.

Ship to: ___HCP* address ___Patient address

*When shipping to HCP, trial product may only be shipped to prescribing HCP.

Patient Information

Patient First Name | Patient Last Name | Date of Birth (MM/DD/YYYY) / /

Parent/Guardian First Name (if applicable) | Parent/Guardian Last Name (if applicable)

Address (where product will be received; no P.O. boxes) | City | State | ZIP

Email Address | Phone Number

Diagnosis (ICD-9/ICD-10)

Healthcare Provider Information

Healthcare Provider Name | Facility Name

License Number (required by law) | Tax ID Number

Address | City | State | ZIP

Phone Number | Fax Number

Prescribing Information

Patient Weight kg lb

Total ADVATE IUs required for one dose (pharmacy will determine vial potency to fulfill six (6) doses)

Special dosing instructions (optional)

Program Terms and Eligibility

- The FREEDOM OF CHOICE Trial Program for ADVATE provides, at no-cost, patients with Hemophilia A with six (6) doses of ADVATE.
- This free trial offer is solely intended to allow new patients to try ADVATE 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.
- 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.
- To be eligible: 1) patient must have an ICD9 or ICD10 verified diagnosis of Hemophilia A; and 2) be a new patient not currently using ADVATE and who has not previously enrolled in the FREEDOM OF CHOICE Trial Program for ADVATE.
- Free Trial ADVATE may only be delivered to the patient's home (No PO boxes) or HCP.
- Free Trial ADVATE cannot be exported or transferred in exchange for money, other property, or services.
- No portion of the Free Trial ADVATE may be submitted for reimbursement to any third-party payer, including Medicare or Medicaid, either directly or indirectly.
- This program is valid only for residents of the United States.
- Shire reserves the right to change or discontinue this program at any time without notice.
- This program does not constitute a financial assistance or cost-savings program.
- Void where prohibited by law. Void where use is prohibited by your insurance provider.

Please see the ADVATE Indications and Detailed Important Risk Information on page 3.
For additional safety information, click here for Prescribing Information and discuss with your HCP.

Shire

Physician/Prescriber Certification, Authorization, and Release

- I verify that I have obtained consent from my patient to release this information.
- I verify the free trial product will not be exported or transferred in exchange for money, other property, or services. No portion of the free trial will be used for reimbursement purposes, including from Medicare, Medicaid, or any third-party program, which provides cost- or charge-based reimbursement to the participating institution, either directly or indirectly.
- I authorize Shire and its affiliated companies, agents, representatives, and contracted third parties ("Shire and Shire Parties") to contact this patient regarding Shire programs and services and to forward this enrollment form to the dispensing pharmacy for fulfillment.
- I authorize the dispensing pharmacy to share information with Shire and Shire Parties about this patient and to use the above information to process ADVATE provided through this free trial program to my patient.

_____ / / _____

Healthcare Provider Signature (no stamps accepted) Date

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 & 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.

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 Prescribing Information and discuss with your HCP.

Shire