FREEDOM OF CHOICE™
Free Trial Program Enrollment Form

Patients may be eligible to receive 8 free trial doses of ADYNOVATE®

ADYNOVATE
[Antihemophilic Factor (Recombinant), PEGylated]

Fax Document to: **1-866-467-7740**

INSTRUCTIONS:

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 INFORMATION

Patient Name _____ Gender ☐ M ☐ F

Date of Birth (MM/DD/YYYY) _____ ☐ I certify I am new to ADYNOVATE

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 ADYNOVATE Detailed Important Risk Information.
Please click here for ADYNOVATE full Prescribing Information.

Takeda

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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 8 doses of ADYNOVATE. Each dose of ADYNOVATE is packaged with Sterile Water for Injection (sWFI), one BAXJECT III® reconstitution device, and one Package Insert.

PRESCRIBER INFORMATION

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 _____ 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 ADYNOVATE, 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)

ADYNOVATE Dosage: Total IUs Required for One Dose (pharmacy will determine vial potency to fulfill eight [8] doses) _____

PRESCRIBER AUTHORIZATION AND RELEASE (REQUIRED)

By signing this form, I certify that therapy with ADYNOVATE is medically necessary for the patient identified in this enrollment form ("Patient"). I have reviewed the current ADYNOVATE 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 ADYNOVATE 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 _____ **Date** _____

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

Please see page 4 for ADYNOVATE Detailed Important Risk 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 ADYNOVATE® [Antihemophilic Factor (Recombinant), PEGylated], and to determine with their healthcare provider whether ADYNOVATE is right for them. There is no obligation to continue use of ADYNOVATE 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 ADYNOVATE.
3. Free trial of ADYNOVATE 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 ADYNOVATE 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.

ADYNOVATE [ANTIHEMOPHILIC FACTOR (RECOMBINANT), PEGYLATED] IMPORTANT INFORMATION

Indications and Limitations of Use

ADYNOVATE is a human antihemophilic factor indicated in children and adults with hemophilia A (congenital factor VIII deficiency) for:

- On-demand treatment and control of bleeding episodes
- Perioperative management
- Routine prophylaxis to reduce the frequency of bleeding episodes

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

Detailed Important Risk Information

CONTRAINDICATIONS

Prior anaphylactic reaction to ADYNOVATE, to the parent molecule (ADVATE [Antihemophilic Factor (Recombinant)]), mouse or hamster protein, or excipients of ADYNOVATE (e.g. Tris, mannitol, trehalose, glutathione, and/or polysorbate 80).

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions are possible with ADYNOVATE. Allergic-type hypersensitivity reactions, including anaphylaxis, have been reported with other recombinant antihemophilic factor VIII products, including the parent molecule, ADVATE. Early signs of hypersensitivity reactions that can progress to anaphylaxis may include angioedema, chest tightness, dyspnea, wheezing, urticaria, and pruritus. Immediately discontinue administration and initiate appropriate treatment if hypersensitivity reactions occur.

Neutralizing Antibodies

Formation of neutralizing antibodies (inhibitors) to factor VIII can occur following administration of ADYNOVATE. Monitor patients regularly for the development of factor VIII inhibitors by appropriate clinical observations and laboratory tests. Perform an assay that measures factor VIII inhibitor concentration if the plasma factor VIII level fails to increase as expected, or if bleeding is not controlled with expected dose.

ADVERSE REACTIONS

The most common adverse reactions (≥1% of subjects) reported in the clinical studies were headache and nausea.

Please click here for ADYNOVATE full Prescribing Information.