# Changes to Your FVIII Therapy

## Are You Taking HEMOFIL® M or RECOMBINATE®?

### Important Information for Patients

**If you take HEMOFIL M [Antihemophilic Factor (Human), Method M, Monoclonal Purified] or RECOMBINATE [Antihemophilic Factor (Recombinant)] as part of your hemophilia A treatment, we have important information to share with you.**

**We have made the difficult decision to globally discontinue these medicines but will continue to provide them until the supply is used up or expired in mid-2026. Exact timing will vary based on potency and demand. It is important to note there is no quality issue with either HEMOFIL M or RECOMBINATE and that their safety and efficacy profiles remain consistent with the product Prescribing Information.**

**We understand that this decision directly impacts patients like you and are here to support you through your transition. Additionally, we encourage you to consult with your healthcare teams now to allow time to develop longer-term treatment plans.**

**Please read this brochure to learn about other FVIII options from Takeda.**

ADVATE [Antihemophilic Factor (Recombinant)]

ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated]

**IMPORTANT INFORMATION**

**What is ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated], ADVATE [Antihemophilic Factor (Recombinant)], RECOMBINATE [Antihemophilic Factor (Recombinant)] and HEMOFIL M [Antihemophilic Factor (Human), Method M, Monoclonal Purified]?**

- ADYNOVATE and ADVATE are 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).
- RECOMBINATE and HEMOFIL M are used to prevent and control bleeding in people with hemophilia A.
- Your healthcare provider (HCP) may give you ADYNOVATE, ADVATE or RECOMBINATE when you have surgery.
- ADYNOVATE and ADVATE can each reduce the number of bleeding episodes when used regularly (prophylaxis).

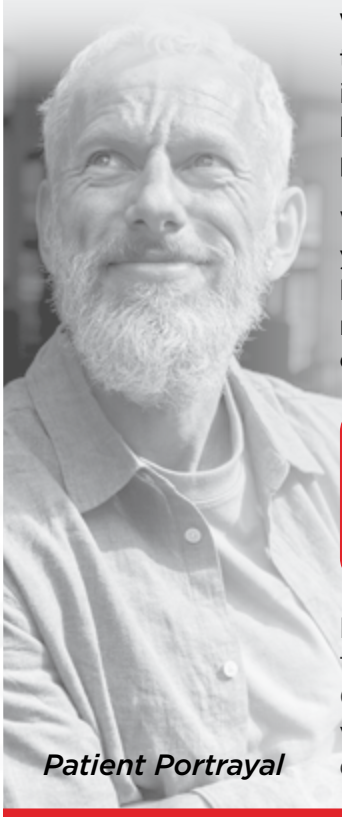
ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M are not used to treat von Willebrand disease.

***Please click for Full Prescribing Information for ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M and discuss with your HCP.***

Takeda

# A Transition of Therapy May Be Difficult

## TAKEDA has options for you



*Patient Portrayal*

**When you're ready to consider options, TAKEDA is here to support you** through this transition. For more than 70 years, we've pioneered innovations including RECOMBINATE, the first recombinant FVIII product in the US and have continued to work hard to improve the standard of care for hemophilia patients like you. Our commitment to your health hasn't changed.

We recognize how long you have relied on HEMOFIL M and RECOMBINATE for your hemophilia A therapy so please know that this was not a decision we made lightly. As the treatment landscape evolves, we decided to discontinue these medicines as hemophilia patients continue to transition to alternate treatment options including those within our Hematology portfolio.

**When you are ready, please consider two products in our Takeda factor VIII family that are similar to HEMOFIL M and RECOMBINATE. ADVATE and ADYNOVATE are widely used today and may meet your individual needs.**

For more information, review this brochure, speak with your healthcare team, and visit HemophiliaJourney.com or reach out to your existing Community Education Specialist from Takeda. For contact information visit advate.com/community-specialist. And know, we will make every effort to help you get the resources and education you may need.

**We would be honored to continue to be part of your journey.**

**DETAILED IMPORTANT RISK INFORMATION: ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M**

**Who should not use ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M?**

*Do not use ADYNOVATE or ADVATE if you:*
- Are allergic to mouse or hamster proteins.
- Are allergic to any ingredients in ADYNOVATE or ADVATE.

*Do not use RECOMBINATE if you:*
- Are allergic to mouse, hamster or bovine proteins.
- Are allergic to any ingredients in RECOMBINATE.

*Do not use HEMOFIL M if you:*
- Are allergic to mice.
- Are allergic to any ingredients in HEMOFIL M.

Tell your HCP if you are pregnant or breastfeeding because ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M may not be right for you.

***Please click for Full Prescribing Information for ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M and discuss with your HCP.***

Takeda

# Explore our hemophilia A products

## What to Know

### For Adults and Children With Hemophilia A

| | TO BE DISCONTINUED | | | |
|---|---|---|---|---|
| | HEMOFIL M | RECOMBINATE | ADVATE | ADYNOVATE |
| **What is it?** | HEMOFIL M is a clotting factor replacement made from human plasma | First recombinant FVIII product in the US | Most widely used FVIII product in the US* with proven efficacy and safety profiles | Built on ADVATE but has an extended half-life so it lasts longer in the body than ADVATE |
| **When was it approved?** | 1966 | 1992 | 2003 | 2015 |
| **What type of FVIII is it?** | Plasma-derived | Recombinant | 3rd generation recombinant standard half-life | 3rd generation recombinant extended half-life |
| **How can it be used?** | On demand and surgery | On demand and surgery | On demand, surgery and/or prophylaxis | |
| **How is it dosed?** | Please see PI | Please see PI | **Prophylaxis** every other day (3 to 4 times weekly), alternatively every 3rd day; **on demand and surgery**, please see PI | **Prophylaxis** twice weekly dosing, same 2 days each week; **on demand and surgery**, please see PI |
| **How is it mixed?** | Double-ended needle | BAXJECT® II *15 reconstitution steps* | BAXJECT III® *3 reconstitution steps* | |
| **Is there coverage?** | 99%† commercial coverage | | Covered on 99%† of commercial and Medicaid health plans | |

**For full dosing information, please see each product's Full Prescribing Information.**

*Based on units sold as of July 2022.

Source: FINGERTIP FORMULARY® as of 3/08/23; is subject to change without notice by a health plan or state.

†Product coverage divided by total therapeutic coverage, based on the Rx and Medicaid coverage using DRG medical lives.

**DETAILED IMPORTANT RISK INFORMATION: ADYNOVATE, ADVATE, RECOMBINATE AND HEMOFIL M**

**What should I tell my HCP before using ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M?**

*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 mouse, hamster or bovine proteins.
- Are breastfeeding. It is not known if ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M pass into your milk or if they can harm your baby.
- Are or become pregnant. It is not known if ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M may harm your unborn baby.
- Have been told that you have inhibitors to factor VIII (because ADYNOVATE, ADVATE, RECOMBINATE, and HEMOFIL M may not work for you).

***Please click for Full Prescribing Information for ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M and discuss with your HCP.***

Takeda

# Learn about your Takeda FVIII options

## ADVATE® and ADYNOVATE®

**Both ADVATE and ADYNOVATE can be taken to help:**

| Prevent bleeding events (known as "prophylaxis") | Control bleeding events (known as "on demand") | With surgeries |
|---|---|---|

**ADVATE**, available for the past 20 years, is the most widely used FVIII in the US* (with over 43 billion IUs distributed globally). **ADVATE**, #1 FVIII product used for breakthrough bleeds in patients on non-factor therapy†

**advate.com**

**ADYNOVATE**, with over 3.8 billion IUs used globally**, was built on the **ADVATE** molecule but with twice-weekly dosing

**adynovate.com**

IU, international unit.

*As of July 2022. **As of November 2022. †Based on units sold from DSA-SP 12-month units data (Oct 2019 to Sept 2024). DSP-SP covers ~40% of the market.

## Do you have questions? We have answers!

1. Reach out to a **Community Education Specialist.** Find one near you by clicking **here**
2. Visit HemophiliaJourney.com to learn more
3. Visit ADVATE.com and ADYNOVATE.com

**Scroll down to learn more about patients who switched to ADVATE or ADYNOVATE.**

**DETAILED IMPORTANT RISK INFORMATION: ADYNOVATE, ADVATE, RECOMBINATE AND HEMOFIL M**

**What important information do I need to know about ADYNOVATE, ADVATE, RECOMBINATE, and HEMOFIL M?**

- You can have an allergic reaction to ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M. Call your healthcare provider right away and stop treatment if you get a rash or hives, itching, flushing, facial swelling, tightness of the throat, chest pain or tightness, wheezing, difficulty breathing, lightheadedness, dizziness, nausea or fainting.
- Do not attempt to infuse yourself with ADYNOVATE, ADVATE, RECOMBINATE or HEMOFIL M unless you have been taught by your HCP or hemophilia center.
- Because HEMOFIL M is made from human blood, it may carry a risk of transmitting infectious agents, such as parvovirus B19, hepatitis A and Creutzfeldt-Jakob disease agent. Symptoms of parvovirus B19 infection include fever, drowsiness, chills and runny nose followed about two weeks later by a rash and joint pain. Symptoms of hepatitis A may include several days to weeks of poor appetite, tiredness and low-grade fever followed by nausea, vomiting, stomach pain, dark urine and a yellowed complexion. Discontinue use of HEMOFIL M and contact your healthcare provider right away if such symptoms occur. Any infections your doctor thinks may have been transmitted by this product should be reported to Takeda Pharmaceuticals U.S.A., Inc. at 1-877-TAKEDA-7 (1-877-825-3327) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

***Please click for Full Prescribing Information for ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M and discuss with your HCP.***

Takeda

# ADVATE: Efficacy and Safety Data Including Those Who Transitioned From HEMOFIL M or RECOMBINATE

## CLINICAL STUDY DESIGN

ADVATE on-demand use was studied in a clinical trial of 111 people 10 years and older with moderate to severe hemophilia A. Subjects took ADVATE on demand to treat a total of 510 bleeding episodes in addition to their regular prophylaxis treatment (3 to 4 times per week). Investigators rated the quality of the on demand treatment response using a scale of Excellent, Good, Fair or None.

| | On-Demand Bleed Control | On-Demand Bleed Control Rating | Prophylaxis Efficacy Results | Safety Data |
|---|---|---|---|---|
| **ADVATE: Efficacy and Safety Study Results (N=111)** | **93%** of 510 bleeding episodes were **controlled with 1 or 2 infusions** | **86%** of 510 bleeding episodes were **rated as Excellent or Good*** | **2.3** **Overall Median ABR (n=107)** | **1** **Inhibitor** developed by 1 patient (temporary). No patient experienced a drug-related serious adverse event |
| **Are you taking HEMOFIL M?** Post-hoc subgroup analysis of patients who transitioned from HEMOFIL M to ADVATE (n=9) | **96%** of 24 bleeding episodes were **controlled with 1 or 2 infusions** | **100%** of 24 bleeding episodes were **rated as Excellent or Good*** | **2.1** **Overall Median ABR** | **0** **Inhibitors** developed. No patient experienced a drug-related serious adverse event |
| **Are you taking RECOMBINATE?** Post-hoc subgroup analysis of patients who transitioned from RECOMBINATE to ADVATE (n=65) | **93%** of 316 bleeding episodes were **controlled with 1 or 2 infusions** | **91%** of 316 bleeding episodes were **rated as Excellent or Good*** | **2.5** **Overall Median ABR** | **0** **Inhibitors** developed. No patient experienced a drug-related serious adverse event |

***Post-hoc Analysis Limitations***

This observational analysis with small sample size was not designed to find differences between the analyzed subgroups and full trial population, and all comparisons are descriptive.

*** What does an Excellent or Good rating mean in these ADVATE clinical studies?**

- **An Excellent rating** means there was abrupt pain relief and/or clear improvement in symptoms within approximately 8 hours after 1 infusion.
- **A Good rating** means there was definite pain relief and/or improvement in symptoms within approximately 8 hours after an infusion, but possibly requiring more than 1 infusion.

ABR is an acronym for Annualized Bleed Rate. This is a measurement of how many total bleeds a person had over one year's time. Median is defined as the middle number in a list of numbers arranged in numerical order.

## DETAILED IMPORTANT RISK INFORMATION: ADYNOVATE, ADVATE, RECOMBINATE AND HEMOFIL M

### What else should I know about ADYNOVATE, ADVATE, RECOMBINATE, HEMOFIL M 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, ADVATE, RECOMBINATE, and HEMOFIL M 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.

**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.

**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.

***Please click for Full Prescribing Information for ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M and discuss with your HCP.***

Takeda

# ADYNOVATE: Efficacy and Safety Data Including Those Who Transitioned From HEMOFIL M or RECOMBINATE

## CLINICAL STUDY DESIGN

A clinical trial of 137 previously treated patients (age 12 years and older) with severe hemophilia A evaluated how well ADYNOVATE worked over 6 months, in both twice-weekly prophylaxis and on-demand use. 120 patients received a prophylaxis dose of 40-50 IU/kg twice a week, and 17 patients received an on-demand dose of 10-60 IU/kg. The primary goal of the study was to compare the annualized bleed rates in the patients receiving prophylaxis and those receiving on-demand treatment.

| | On-Demand Bleed Control | On-Demand Bleed Control Rating | Prophylaxis Efficacy Results | Safety Data |
|---|---|---|---|---|
| **ADYNOVATE: Efficacy and Safety Study Results (N=137)** | **96%** of 591 bleeding episodes were **controlled with 1 or 2 infusions** | **95%** of 591 bleeding episodes were **rated as Excellent or Good*** | **1.9** **Overall Median ABR (n = 120)** | **1** **Inhibitors** developed. No patient experienced a drug-related serious adverse event |
| **Are you taking HEMOFIL M?** Post-hoc subgroup analysis of patients who transitioned from HEMOFIL M to ADYNOVATE (n=10) | **93%** of 45 bleeding episodes were **controlled with 1 or 2 infusions** | **100%** of 45 bleeding episodes were **rated as Excellent or Good*** | **2.0** **Overall Median ABR (n=8)** | **0** **Inhibitors** developed. No patient experienced a drug-related serious adverse event |
| **Are you taking RECOMBINATE?** Post-hoc subgroup analysis of patients who transitioned from RECOMBINATE to ADYNOVATE (n=7) | **100%** of 25 bleeding episodes were **controlled with 1 or 2 infusions** | **100%** of 25 bleeding episodes were **rated as Excellent or Good*** | **2.0** **Overall Median ABR** | **0** **Inhibitors** developed. No patient experienced a drug-related serious adverse event |

***Post-hoc Analysis Limitations***

This observational analysis with small sample size was not designed to find differences between the analyzed subgroups and full trial population, and all comparisons are descriptive.

*** What does an Excellent or Good rating mean in these ADYNOVATE clinical studies?**

- **An Excellent rating** means there was a full relief of pain and objective signs that bleeding has stopped.
- **A Good rating** means there was definite pain relief and/or improvement in bleeding.

ABR is an acronym for Annualized Bleed Rate. This is a measurement of how many total bleeds a person had over one year's time. Median is defined as the middle number in a list of numbers arranged in numerical order.

## DETAILED IMPORTANT RISK INFORMATION: ADYNOVATE, ADVATE, RECOMBINATE AND HEMOFIL M

What are possible side effects of ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M?

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, ADVATE, RECOMBINATE, and HEMOFIL M 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.

**RECOMBINATE**: The most common side effects reported during clinical studies with RECOMBINATE include: chills, flushing, rash and nose bleeds.

**HEMOFIL M**: The most common side effects reported during clinical studies with HEMOFIL M include: Factor VIII inhibitors, dizziness, headache, unusual taste, fever and infusion site inflammation.

***Please click for Full Prescribing Information for ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M and discuss with your HCP.***

Takeda

# Meet BAXJECT III

**Changing to a different device may be challenging, but the BAXJECT III device has an easy, single-vial activation process with fewer steps. And we are here with resources on how to use it.**

---

## ADVATE and ADYNOVATE are prepared with the easy-to-activate BAXJECT III Reconstitution System.

### For Patients Taking HEMOFIL M

Unlike the double-ended needle reconstitution for HEMOFIL M, the BAXJECT III reconstitutes your medication with an easy 1-step activation process.

### For Patients Taking RECOMBINATE

ADVATE and ADYNOVATE both come prepackaged with the BAXJECT III for an easy, single-vial, 1-step activation process with no need to disinfect.

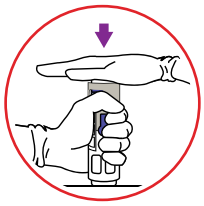
### Watch how the BAXJECT III device works

Watch the video for step-by-step instructions on how to reconstitute ADVATE or ADYNOVATE with the BAXJECT III Reconstitution System.

**Do not attempt to infuse yourself with ADVATE or ADYNOVATE unless you have been taught by your HCP or hemophilia treatment center.**

Refer to the Instructions for Use for ADVATE here and for ADYNOVATE here.

### How to Reconstitute ADVATE and ADYNOVATE

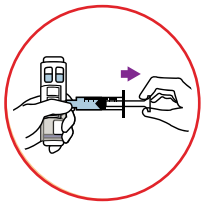


**PRESS**

Press firmly and system will be activated

**SWIRL**

A gentle swirl allows for proper mixing



**FLIP & WITHDRAW**

The dose is ready to be withdrawn from the system

**DETAILED IMPORTANT RISK INFORMATION: ADYNOVATE, ADVATE, RECOMBINATE AND HEMOFIL M**

**Tell your HCP about any side effects that bother you or do not go away or if your bleeding does not stop after taking ADYNOVATE, ADVATE, RECOMBINATE or HEMOFIL M. 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.**

***Please click for Full Prescribing Information for ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M and discuss with your HCP.***

Takeda

# Takeda is here to support you because we know change isn't always easy

Takeda has a variety of resources to help patients who have been prescribed ADVATE or ADYNOVATE, including information and resources regarding their treatment.

**ADVATE and ADYNOVATE are covered by over 99%* of commercial and Medicaid health plans.†**

The FREEDOM OF CHOICE Trial Program for ADVATE and ADYNOVATE provides **eligible patients with hemophilia A with trial doses at no cost.**

ADVATE **6** Free-trial doses

ADYNOVATE **8** Free-trial doses

**Details you need to know:**

- This program is available to new ADVATE and ADYNOVATE patients only‡
- Patients must work with their healthcare provider and Takeda to participate
- Must be for an approved use
- Visit the registration forms for **ADVATE** and **ADYNOVATE** to learn more

*Product coverage divided by total therapeutic coverage, based on the Rx and Medicaid coverage using DRG medical lives.

†Source: FINGERTIP FORMULARY®, as of 03/08/2023, is subject to change without notice by a health plan or state.

‡Other restrictions may apply. See Program Terms & Eligibility.

**IMPORTANT INFORMATION**

**What is ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated], ADVATE [Antihemophilic Factor (Recombinant)], RECOMBINATE [Antihemophilic Factor (Recombinant)] and HEMOFIL M [Antihemophilic Factor (Human), Method M, Monoclonal Purified]?**

- ADYNOVATE and ADVATE are 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).
- RECOMBINATE and HEMOFIL M are used to prevent and control bleeding in people with hemophilia A.
- Your healthcare provider (HCP) may give you ADYNOVATE, ADVATE or RECOMBINATE when you have surgery.
- ADYNOVATE and ADVATE can each reduce the number of bleeding episodes when used regularly (prophylaxis).

ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M are not used to treat von Willebrand disease.

***Please click for Full Prescribing Information for ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M and discuss with your HCP.***

Takeda

# Welcome to Takeda Patient Support

## Support specialists you can count on

When you're prescribed ADVATE or ADYNOVATE, Takeda Patient Support is here for you. Our goal is to make your treatment experience a little easier.

Shortly after enrolling, you'll receive a call from us to welcome you to the program. We'll let you know what to expect and explain how we can assist you when needed. Our support specialists are here to help you get the answers and information you need. Some of the ways we can assist include:

- Offering insurance support by reviewing your coverage and helping you understand what financial options may be available
- Enrolling you in the Takeda Patient Support Co-Pay Assistance Program, if you're eligible*
- Working with your specialty pharmacy (or site of care) to help you receive your prescribed Takeda treatment (if available for your therapy)
- Arranging for nursing support if you have questions about your condition and your prescribed Takeda treatment (if available for your therapy)

We offer additional support for your prescribed Takeda treatment when you need it, including:

- Directing you to community support resources and education
- Providing you with tips and timely information throughout your prescribed Takeda treatment

*To be eligible, you must be enrolled in Takeda Patient Support and have commercial insurance. Other terms and conditions apply. Call us for more details.

### WANT TO CONNECT?

Dedicated teams are available to assist you Monday through Friday with extended evening business hours. Visit TakedaPatientSupport.com for contact information.

**Not enrolled?** Visit TakedaPatientSupport.com for information on how to enroll.

If English is not your preferred language, let us know. We may be able to assist you in the language of your choosing.

Takeda Patient Support
Your Source for Education and Access

# Takeda Patient Support

**The Takeda Patient Support Co-Pay Assistance Program may help you save on your prescribed Takeda treatment.***

The program can cover up to 100% of your out-of-pocket co-pay costs, if you're eligible. To be eligible for this program, you must:

1. **Be prescribed a Takeda treatment for a condition that's approved by the Food and Drug Administration (FDA) to treat.** This is called an "approved indication." Ask your healthcare provider if you're not sure.
2. **Have commercial insurance.** This includes Health Insurance Marketplace plans.
   - Commercial insurance does not include Medicare, Medicaid, Veterans Affairs (VA), or other federal or state health plans
3. **Be enrolled in Takeda Patient Support.**

**If you can't afford your treatment,** we may be able to connect you to programs that may help.

*To be eligible, you must be enrolled in Takeda Patient Support and have commercial insurance. Other terms and conditions apply. Call us for more details.

## WANT TO CONNECT?

Dedicated teams are available to assist you Monday through Friday with extended evening business hours. Visit TakedaPatientSupport.com for contact information.

***IMPORTANT NOTICE:** Takeda's Co-pay Assistance Program ("the Program") provides financial support for commercially insured patients who qualify for the Program. Participation in the Program and provision of financial support is subject to all Program terms and conditions, including but not limited to eligibility requirements, the Program maximum benefit per claim and the annual calendar year Program maximum ("Annual Program Maximum"). The Annual Program Maximum for your prescribed Takeda product can be found by visiting: www.takedapatientsupport.com/copay.

By enrolling in the Program, you agree that the Program is intended solely for the benefit of you—not health plans and/or their partners. Further, you agree to comply with all applicable requirements of your health plan. The Program cannot be used if the patient is a beneficiary of, or any part of the prescription is covered by: 1) any federal, state, or government-funded healthcare program (Medicare, Medicare Advantage, Medicaid, TRICARE, etc.), including a state pharmaceutical assistance program (the Federal Employees Health Benefit (FEHB) Program is not a government-funded healthcare program for the purpose of this offer), 2) the Medicare Prescription Drug Program (Part D), or if the patient is currently in the coverage gap, or 3) insurance that is paying the entire cost of the prescription. No claim for reimbursement of the out-of-pocket expense amount covered by the Program shall be submitted to any third-party payer, whether public or private.

Some health plans have established programs referred to as 'co-pay maximizer' programs. A co-pay maximizer program is one in which the amount of a patient's out-of-pocket costs is adjusted to reflect the availability of support offered by a manufacturer's co-pay assistance program. If you are enrolled in a co-pay maximizer program, your Annual Program Maximum may vary over time to ensure the program funds are used for your benefit (for the benefit of the patient). Takeda also reserves the right to reduce or eliminate the co-pay assistance available to patients enrolled in an insurance plan that utilizes a co-pay maximizer program.

If you learn your health plan has implemented a co-pay maximizer program, you agree to notify the Program immediately by calling 1-888-229-8379. It may be possible that you are unaware whether you are subject to a co-pay maximizer program when you enroll or re-enroll in the Program. Takeda will monitor program utilization data and reserves the right to discontinue assistance under the Program at any time if Takeda determines that you are subject to a co-pay maximizer, or similar program.

The Program only applies in the United States, including Puerto Rico and other U.S. territories, and does not apply where prohibited by law, taxed, or restricted. This does not constitute health insurance. Void where use is prohibited by your insurance provider. If your insurance situation changes you must notify the Program immediately at 1-888-229-8379. Coverage of certain administration charges will not apply for patients residing in states where it is prohibited by law.

This Program offer is not transferable and is limited to one offer per person and may not be combined with any other coupon, discount, prescription savings card, rebate, free trial, patient assistance, co-pay maximizer, alternative funding program, co-pay accumulator, or other offer, including those from third parties and companies that help insurers or health plan manage costs. Not valid if reproduced.

By utilizing the Program, you hereby accept and agree to abide by these terms and conditions. Any individual or entity who enrolls or assists in the enrollment of a patient in the Program represents that the patient meets the eligibility criteria and other requirements described herein. You must meet the Program eligibility requirements every time you use the Program. Takeda reserves the right to rescind, revoke, or amend the Program at any time without notice, and other terms and conditions may apply.

Takeda Patient Support
Your Source for Education and Access

# Are You Taking HEMOFIL M or RECOMBINATE?

## Important Information to Know

### What's happening?

We made the difficult decision to globally discontinue HEMOFIL M and RECOMBINATE. We intend to supply HEMOFIL M and RECOMBINATE to patients currently receiving these medicines until inventory is depleted or expired in mid-2026. We are here to support you through this transition.

### Our Available Options

**ADVATE** and **ADYNOVATE** are both proven treatment options that offer similar efficacy and safety profiles for patients with hemophilia A. **ADVATE**, available for the past 20 years, is the most widely used FVIII product in the US.* It is also the #1 FVIII used for breakthrough bleeds in patients on non-factor therapy.† **ADYNOVATE**, built on **ADVATE**, has an extended half-life and a twice-weekly dosing.

### An Easy One-Step Activation Device

When changing treatments, transitioning devices may be challenging, but reconstitution with Baxject III offers an easy one-step activation process.

***Press. Swirl. Flip & Withdraw.***

### Free-Trial Program

We at Takeda want to support you through this transition. The Freedom of Choice Trial Program allows eligible patients to try **ADVATE** or **ADYNOVATE** at no cost.

**Visit HemophiliaJourney.com for more information.**

*Based on units sold as of July 2022. †Based on Units sold from DSA-SP 12-month units data (Oct 2019 to Sept 2024). DSP-SP covers ~40% of the market.

**IMPORTANT INFORMATION**

**What is ADYNOVATE [Antihemophilic Factor (Recombinant), PEGylated], ADVATE [Antihemophilic Factor (Recombinant)], RECOMBINATE [Antihemophilic Factor (Recombinant)] and HEMOFIL M [Antihemophilic Factor (Human), Method M, Monoclonal Purified]?**

- ADYNOVATE and ADVATE are 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).
- RECOMBINATE and HEMOFIL M are used to prevent and control bleeding in people with hemophilia A.
- Your healthcare provider (HCP) may give you ADYNOVATE, ADVATE or RECOMBINATE when you have surgery.
- ADYNOVATE and ADVATE can each reduce the number of bleeding episodes when used regularly (prophylaxis).

ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M are not used to treat von Willebrand disease.

©2025 Takeda Pharmaceuticals U.S.A., Inc., 500 Kendall Street, Cambridge, MA 02142. 1-877-TAKEDA-7 (1-877-825-3327). Takeda, the Takeda logo and the Takeda Patient Support Logo™ are trademarks or registered trademarks of Takeda Pharmaceutical Company Limited. ADVATE, ADYNOVATE, BAXJECT, and BAXJECT III, FREEDOM OF CHOICE, HEMOFIL and RECOMBINATE are trademarks or registered trademarks of Baxalta Incorporated. US-XMP-3137v2.0 03/25

***Please click for Full Prescribing Information for ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M and discuss with your HCP.***

Takeda