Frequently Asked Questions

We understand that the decision to globally discontinue HEMOFIL® M [Antihemophilic Factor (Human), Method M, Monoclonal Purified] and RECOMBINATE® [Antihemophilic Factor (Recombinant)] directly impacts patients who depend on these medicines.

Rest assured, we are here to support you during this transition. Please see below for answers to some frequently asked questions or visit HemophiliaJourney.com for more information.

General Information

1. Why are HEMOFIL M and RECOMBINATE being discontinued?

This was not a decision we made lightly. As the treatment landscape evolves, hemophilia patients continue to transition to alternate treatment options in the space, including those within our own Hematology portfolio, and we ultimately made the decision to discontinue these medicines to enable us to best serve patients long-term.

2. What is Takeda doing to minimize the patient impact of this decision?

We understand that this decision directly impacts patients who depend on these therapies for the management of their condition and are here to support the hemophilia community during this transition.

We intend to supply HEMOFIL M and RECOMBINATE to patients currently receiving these medicines until inventory is depleted or expired in mid-2026. Exact timing will vary based on potency and demand. We encourage patients to consult with their healthcare teams now to allow time to develop longer-term individual treatment plans.

We are proud to offer multiple available options within our factor VIII portfolio, namely ADVATE® [Antihemophilic Factor (Recombinant)] and ADYNOVATE® [Antihemophilic Factor (Recombinant), PEGylated], that may meet patients' individual needs and are similar to HEMOFIL M and RECOMBINATE.

3. How long will patients being treated with HEMOFIL M and/or RECOMBINATE have until they need to transition to an alternate therapy?

While the exact timing will vary based on potency and demand, we currently anticipate being able to supply patients with HEMOFIL M and RECOMBINATE until mid-2026. With this in mind, we are communicating this decision now to allow time for patients to consult with their healthcare teams now to allow time to develop longer-term individual treatment plans.

4. What is ADYNOVATE, ADVATE, RECOMBINATE and HEMOFIL M?

- 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.

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Alternative Takeda Therapies

1. Are there alternative Takeda therapies available?

For more than 70 years, we've pioneered innovations and worked tirelessly to improve the standard of care for hemophilia patients. We are proud of our legacy and the positive patient experiences across our factor VIII portfolio, which includes ADVATE and ADYNOVATE.

Like HEMOFIL M and RECOMBINATE, ADVATE and ADYNOVATE are trusted, full-length factor VIII treatment options with established safety and efficacy.[1]

ADVATE has been proven effective for prophylaxis, on-demand and surgical use in children and adults with hemophilia A and has an established efficacy and safety profile backed by 20 years of real-world experience and 15 prospective studies.[2,3] ADVATE has more single-dose infusion options than any other factor VIII therapy – with 11 potencies and two vial sizes – giving patients and their healthcare providers personalized dosing options.[2,3] ADVATE is the most widely used factor VIII therapy in the U.S. with 43 billion International Units (IUs) sold globally.[*2] ADVATE is the #1 factor VIII treatment used for breakthrough bleeds in patients on non-factor therapy.[†2]

ADYNOVATE is an established, extended half-life factor VIII therapy built on the proven molecule of ADVATE. ADYNOVATE is a twice-weekly treatment with seven available potencies that can be personalized to fit patients' lifestyles. Initially approved in 2015, ADYNOVATE is indicated for prophylaxis, on-demand and surgical use in children and adults with hemophilia A.[4] Patients should contact their healthcare provider to discuss if ADVATE or ADYNOVATE is right for them.

2. 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.

Continue reading for additional Detailed Important Risk Information.

3. Where can I learn more about patients who have switched from HEMOFIL M or RECOMBINATE to ADVATE or ADYNOVATE?

You can learn more about patients who have transitioned from HEMOFIL M or RECOMBINATE to ADVATE or ADYNOVATE by viewing this brochure, where you'll find detailed information and resources to support you during this time.

*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

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4. Do ADVATE and ADYNOVATE use the same reconstitution device as HEMOFIL M or RECOMBINATE? How do patients self-infuse using the BAXJECT III® reconstitution device?

ADVATE and ADYNOVATE are administered via intravenous injection following reconstitution with the BAXJECT III reconstitution device. The BAXJECT III reconstitution device is similar to the BAXJECT II® reconstitution device used with RECOMBINATE but has a single-vial, one-step activation process.[3,4] Step-by-step instructions on how to use the BAXJECT III are available for ADVATE and ADYNOVATE.

For complete Instructions for Use, please see the Full Prescribing Information for ADVATE and ADYNOVATE.

5. Does Takeda offer other plasma-based therapies for hemophilia A?

No, we offer multiple effective recombinant factor VIII therapies with established safety profiles for the treatment of hemophilia A, namely ADVATE and ADYNOVATE.[2,3,4]

6. Are recombinant therapies safe and effective?

Recombinant factor VIII therapies have been used to treat hemophilia A since 1992 and were developed to reduce the risk of exposure to blood-borne pathogens.[5] These therapies are made in a lab using pharmaceutical technology instead of human factor collected through plasma donation, which is used to create plasma-derived factor VIII therapies.

ADVATE and ADYNOVATE are both recombinant factor VIII therapies built on the same cell line as RECOMBINATE with modifications to the cell culture process to eliminate the need for human or animal-derived raw materials, resulting in virtually no risk of pathogenic virus transmission.[3,4,6]

For more information about the safety and efficacy profiles of these therapies, please visit ADVATE.com and ADYNOVATE.com.

Takeda Patient Support

1. Will Takeda Patient Support be available for patients who transition from HEMOFIL M and RECOMBINATE to other Takeda therapies?

Yes, for patients prescribed a Takeda treatment, Takeda Patient Support is dedicated to providing the answers, resources and tools they need. Our support specialists can:

- Enroll patients in the Takeda Patient Support Co-Pay Assistance Program, if they qualify
- Work with their specialty pharmacy or site of care to help them receive their prescribed Takeda treatment
- Offer insurance support by reviewing their coverage and helping patients understand what financial options may be available
- Direct patients to community support resources and education
- Provide patients with tips and timely information throughout their Takeda treatment

To learn more about Takeda Patient Support, visit TakedaPatientSupport.com or call 1-888-229-8379, Monday through Friday, 8 AM to 8 PM ET.

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2. Does Takeda offer co-pay assistance for ADVATE and ADYNOVATE?

The Takeda Patient Support Co-Pay Assistance Program can help patients save on their prescribed ADVATE or ADYNOVATE. The program may cover up to 100% of their out-of-pocket co-pay costs, if they're eligible.* To be eligible for this program, patients must:

- Be prescribed a Takeda treatment for a condition it's approved to treat by the U.S. Food and Drug Administration (FDA)
- Have commercial insurance. This includes Health Insurance Marketplace plans. This does not include Medicare, Medicaid, Veterans Affairs (VA), or other federal or state health plans
- Be enrolled in Takeda Patient Support

***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"). Full terms and conditions, including the Annual Program Maximum for your prescribed Takeda product can be found by visiting: https://www.takedapatientsupport.com/copay.

Detailed Important Risk Information

1. 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).

2. 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.

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3. 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.

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

- **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.
- **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.

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.

References:

1. Baunsgaard D. et al. A comparative analysis of heterogeneity in commercially available recombinant factor VIII products. Haemophilia. 2018;880-887. https://doi.org/10.1111/hae.13497
2. Takeda Data on File.
3. ADVATE Prescribing Information
4. ADYNOVATE Prescribing Information
5. Pipe S. Consideration in Hemophilia Therapy Selection. Seminars in Hematology. 2006;43(Suppl 3):S23-S27
6. RECOMBINATE PI