



March 2026

Important Product Supply Update to Global Discontinuation of HEMOFIL® M [Antihemophilic Factor (Human), Method M, Monoclonal Purified] and RECOMBINATE® [Antihemophilic Factor (Recombinant)]

Dear Valued Patient,

As announced in March 2025, Takeda has decided to globally discontinue HEMOFIL® M [Antihemophilic Factor (Human), Method M, Monoclonal Purified] and RECOMBINATE® [Antihemophilic Factor (Recombinant)]. This was not a decision we made lightly. We understand that this directly impacts you and are here to support the hemophilia community during this transition.

I'm reaching out today to update you on product supply timelines:

- We intend to supply HEMOFIL® M to patients already receiving the medicine through **September 2026**.
- We intend to supply RECOMBINATE® to patients already receiving the medicine through **September 2026**, except for RECOMBINATE® 250 IU and 2000 IU, which we anticipate will be available through **March 2027**.

Takeda remains committed to supporting impacted patients throughout this transition. Please be assured that there is no quality issue with either HEMOFIL M or RECOMBINATE and that their safety and efficacy remain consistent with the product Prescribing Information.

Transitioning to Alternative Treatment

We recommend having discussions with your healthcare team to create a longer-term, alternative treatment plan.

For more than 70 years, we've pioneered innovations and worked tirelessly to improve the standard of care for hemophilia patients. We are proud to offer alternative treatment options within the Takeda factor VIII portfolio, namely ADVATE® [Antihemophilic Factor (Recombinant)] and ADYNOVATE® [Antihemophilic Factor (Recombinant), PEGylated], that may meet your individual needs and are similar to HEMOFIL M and RECOMBINATE. Please visit [ADVATE.com](https://www.advate.com) and [ADYNOVATE.com](https://www.adynovate.com) for more 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 adults and children with hemophilia A (congenital factor VIII deficiency).
- 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 see Detailed Important Risk Information below and discuss with your healthcare provider.

Takeda Support

Our commitment to supporting you throughout this transition is unwavering. For more information, visit <https://www.hemophiliajourney.com/>.

Please contact your healthcare provider directly to discuss alternative treatment plans.

Community Education Specialist Support

Takeda's Community Education Specialists (CES) are a dedicated resource providing tailored education to people who are considering or have been prescribed ADVATE or ADYNOVATE. Find the nearest CES to you by visiting www.advate.com/community-specialist.

For patients prescribed a Takeda treatment, our dedicated Takeda Patient Support team is available to direct you to financial assistance options and insurance support, help you get your medication delivered and help you understand your condition and prescribed Takeda treatment. To learn more about Takeda Patient Support, visit TakedaPatientSupport.com or call 1-888-229-8379, Monday through Friday, 8AM to 8 PM ET.

Reporting Adverse Events

Healthcare providers and patients are encouraged to report adverse reactions and/or quality problems related to HEMOFIL M or RECOMBINATE to Takeda at 1-877-TAKEDA-7 (1-877-825-3327). 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.

This letter is not intended as a complete description of the benefits and risks related to the use of HEMOFIL M, RECOMBINATE, ADVATE and/or ADYNOVATE. Please visit ADVATE.com and ADYNOVATE.com to learn more about our safety and efficacy profiles.

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.

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 pregnant or planning to 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).

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.

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.

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

- **Adynovate:** The common side effects of ADYNOVATE are cough, headache, diarrhea, vomiting, rash, nausea, hives and dizziness. 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.

Sincerely,
Anthea Cherednichenko
Vice President, Franchise Head, U.S. Hematology

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