



Important News Regarding Helixate® FS, Antihemophilic Factor (Recombinant):

Availability and what comes next

Please see Important Safety Information on pages 10–11 and accompanying full prescribing information, including patient product information.

CSL Behring
Biotherapies for Life®

Helixate® FS, Antihemophilic Factor (Recombinant), will no longer be manufactured after December 2017—here's what you need to know

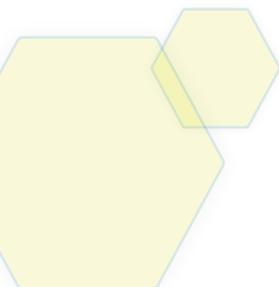
CSL Behring recognizes that Helixate FS has been an important part of managing your hemophilia. After supplying Helixate FS for more than two decades, it was with a great deal of consideration that the decision was made to phase out this product. We created this guide to help answer any questions you may have so you can be prepared to take the next appropriate steps to manage your hemophilia.

How long will Helixate FS be available?

The Factor VIII therapy Helixate FS will **no longer be manufactured after December 2017**. Supply will continue to be **available through early 2019**. You can be assured CSL Behring will continue to provide updates regarding the Helixate FS supply.

Why will Helixate FS no longer be available?

At CSL Behring, we listen to and address the needs of those who rely on our treatment therapies. The hemophilia community deserves innovative therapies built for today. With that in mind, we've put our resources into developing a novel next-generation therapy.



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CSL Behring offers a next-generation treatment option

? I've been using Helixate® FS, Antihemophilic Factor (Recombinant), a long time. What will happen to the CSL Behring AssuranceSM product points I've accumulated?

Any Assurance points you have accumulated by using Helixate FS can be fully transferred to any other hemophilia A therapy produced by CSL Behring, such as AFSTYLA®, Antihemophilic Factor (Recombinant), Single Chain. As you know, Assurance points can be used to help make treatment available in the event of a lapse in insurance coverage.*

It's not too late to sign up for CSL Behring Assurance. Talk to your My SourceSM Care Coordinator at 1-800-676-4266 for more information.

*Terms and conditions apply.

? What is the novel next-generation therapy mentioned above that CSL Behring developed?

CSL Behring has developed long-lasting AFSTYLA, a next-generation Factor VIII therapy, as an effective treatment option for you. AFSTYLA has been FDA approved for dosing 2 or 3 times weekly.



Please see Important Safety Information on pages 10–11 and accompanying full prescribing information, including patient product information.



AFSTYLA[®]
Antihemophilic Factor
(Recombinant), Single Chain



? **What is AFSTYLA and what can it offer me?**

With twice-weekly dosing available, AFSTYLA is the first and only recombinant Factor VIII therapy that delivers proven, long-lasting bleed protection with a novel single-chain design.

- In clinical trials, AFSTYLA demonstrated proven bleed protection with zero median spontaneous bleeds (median AsBR[†]), regardless of dosing schedule and age
- AFSTYLA safety was evaluated in the largest hemophilia A pivotal clinical trial program to date (258 participants)
 - Zero inhibitors observed—low incidence of side effects in clinical trials
 - In clinical trials, dizziness and allergic reactions were the most common side effects
- AFSTYLA is comparable to natural Factor VIII. Once activated in your bloodstream, it is identical to natural Factor VIII

†Annualized spontaneous bleeding rate in clinical trials (interquartile range [IQR]=0–2.4 for patients ≥12 years; 0–2.2 for patients <12 years).

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We want to help make switching easy

? I am enrolled in a patient support program for Helixate® FS, Antihemophilic Factor (Recombinant). Are similar patient support programs available for AFSTYLA®, Antihemophilic Factor (Recombinant), Single Chain?

Yes. In fact, all the support services you have come to rely on and trust with Helixate FS are available with AFSTYLA. Services* include:

- **My Access®**—the co-pay program that provides up to \$12,000 of annual out-of-pocket expenses associated with therapy
- **CSL Behring Patient Assistance ProgramSM**—helps people who are uninsured or underinsured
- **CSL Behring AssuranceSM Program**—helps make treatment available in case of a lapse in insurance coverage
 - Assurance points you have earned with Helixate FS can be fully transferred to your AFSTYLA balance

Talk to your My SourceSM Care Coordinator at 1-800-676-4266, Monday through Friday, 8 AM to 8 PM ET, for more details about these programs and eligibility requirements.

*Terms and conditions apply.



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? If I decide to try AFSTYLA, will I need to learn to use a new reconstitution and transfer device?

No. AFSTYLA uses the same Mix2Vial® needle-free reconstitution and transfer system that you are familiar and comfortable with using to reconstitute Helixate FS.



? If my doctor and I decide that AFSTYLA is an option for me, what's involved in getting started with AFSTYLA and how can I enroll in its support programs?

Getting started is simple:

1. Ask your doctor to **start** you on a free 30-day trial of AFSTYLA
2. With your doctor, **fill out** an AFSTYLA Patient Referral form to enroll you in the AFSTYLA support program and begin a benefits investigation
3. Have your doctor **fax** completed forms to My Source at 1-844-727-2757

Your doctor can visit [AFSTYLA.com/hcp/practice-resources](https://www.afstyla.com/hcp/practice-resources) to download the form, or call My Source at 1-800-676-4266, Monday through Friday, 8 AM to 8 PM ET, for further assistance.

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Important contact information

Who can I ask for further information regarding the availability of Helixate® FS, Antihemophilic Factor (Recombinant)?

Your doctor, specialty pharmacy, or CSL Behring Representative can help you find out about Helixate FS availability in your area. Your My SourceSM Care Coordinator would also be happy to help you find answers to any other Helixate FS questions you may have. You can contact My Source at 1-800-676-4266, Monday through Friday, 8 AM to 8 PM ET.

Where can I find out more about AFSTYLA®, Antihemophilic Factor (Recombinant), Single Chain?

You can sign up for informative updates and learn more about AFSTYLA safety and efficacy at [AFSTYLA.com](https://www.afstyla.com), or you can contact your My Source Care Coordinator at 1-800-676-4266, Monday through Friday, 8 AM to 8 PM ET, with further questions. Ask your doctor if AFSTYLA is right for you.

Our Commitment

CSL Behring has provided Helixate FS to people like you for more than two decades. We will continue to bring you the most up-to-date information about Helixate FS and AFSTYLA.

Your **My Source Care Coordinator** is ready to answer any questions

Call 1-800-676-4266,
Monday through Friday,
8 AM to 8 PM ET

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**Switching therapies
is a big decision**

When talking with your
doctor about the next
steps in your treatment,
we hope you'll
consider AFSTYLA



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Important Safety Information for HELIXATE FS

HELIXATE® FS, Antihemophilic Factor (Recombinant), is a medicine used to replace clotting factor (factor VIII or antihemophilic factor) that is missing in people with hemophilia A.

HELIXATE FS is used to treat and control bleeding in adults and children with hemophilia A. Your healthcare provider might give you HELIXATE FS when you have surgery. HELIXATE FS can reduce the number of bleeding episodes in adults and children when used regularly (prophylaxis), and can reduce the risk of joint damage in children without preexisting joint damage when used regularly.

HELIXATE FS is not used to treat von Willebrand disease.

You should not use HELIXATE FS if you are allergic to rodents (like mice and hamsters) or are allergic to any ingredients of HELIXATE FS.

Tell your healthcare provider if you have been told you have heart disease or are at risk for heart disease.

You could have an allergic reaction to HELIXATE FS. Call your healthcare provider right away and stop treatment if you get rash or hives, itching, tightness of the chest or throat, difficulty breathing, light-headed, dizziness, nausea or a decrease in blood pressure.

Your body can make antibodies against HELIXATE FS, called “inhibitors,” which could stop HELIXATE FS from working properly. Consult with your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to factor VIII.

Other common side effects of HELIXATE FS are local injection-site reactions (pain, swelling, irritation at infusion site) and infections from implanted injection device. Tell your healthcare provider about any side effect that bothers you or does not go away.

Call your healthcare provider right away if bleeding is not controlled after using HELIXATE FS.

Please see the accompanying full prescribing information for HELIXATE FS, including approved patient labeling.

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.



Important Safety Information for AFSTYLA

AFSTYLA®, Antihemophilic Factor (Recombinant), Single Chain, is used to treat and control bleeding episodes in people with hemophilia A. Used regularly (prophylaxis), AFSTYLA can reduce the number of bleeding episodes and the risk of joint damage due to bleeding. Your doctor might also give you AFSTYLA before surgical procedures.

AFSTYLA is administered by intravenous injection into the bloodstream, and can be self-administered or administered by a caregiver. Your healthcare provider or hemophilia treatment center will instruct you on how to do an infusion. Carefully follow prescriber instructions regarding dose and infusion schedule, which are based on your weight and the severity of your condition.

Do not use AFSTYLA if you know you are allergic to any of its ingredients, or to hamster proteins. Tell your healthcare provider if you previously had an allergic reaction to any product containing Factor VIII (FVIII), or have been told you have inhibitors to FVIII, as AFSTYLA might not work for you. Inform your healthcare provider of all medical conditions and problems you have, as well as all medications you are taking.

Immediately stop treatment and contact your healthcare provider if you see signs of an allergic reaction, including a rash or hives, itching, tightness of chest or throat, difficulty breathing, lightheadedness, dizziness, nausea, or a decrease in blood pressure.

Your body can make antibodies, called inhibitors, against FVIII, which could stop AFSTYLA from working properly. You might need to be tested for inhibitors from time to time. Contact your healthcare provider if bleeding does not stop after taking AFSTYLA.

In clinical trials, dizziness and allergic reactions were the most common side effects. However, these are not the only side effects possible. Tell your healthcare provider about any side effect that bothers you or does not go away.

Please see accompanying full prescribing information for AFSTYLA, including patient product information.

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.

What happens once Helixate® FS, Antihemophilic Factor (Recombinant), is no longer manufactured?

- Helixate FS will **no longer be manufactured after December 2017**
 - Supply will continue to be **available through early 2019**
- Instead, consider continuing your treatment with the next-generation Factor VIII therapy: AFSTYLA®, Antihemophilic Factor (Recombinant), Single Chain
 - With twice-weekly dosing available, AFSTYLA is the first and only recombinant Factor VIII that delivers proven, long-lasting bleed protection with a novel single-chain design. AFSTYLA also delivered zero bleeds (median AsBR*) in clinical studies regardless of dosing frequency
- If you decide to switch to AFSTYLA, you will be able to:
 - Transfer your Assurance points
 - Access the same patient support programs you had with Helixate FS
 - Use the same Mix2Vial® device you have been using

Visit
AFSTYLA.com
for more information
and to get a free
discovery kit.



*Annualized spontaneous bleeding rate in clinical trials (interquartile range [IQR]=0–2.4 for patients ≥12 years; 0–2.2 for patients <12 years).

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HELIXATE FS is manufactured by Bayer HealthCare for CSL Behring LLC. AFSTYLA is manufactured by CSL Behring GmbH and distributed by CSL Behring LLC. AFSTYLA® is a registered trademark of CSL Behring Recombinant Facility AG. HELIXATE® FS, Biotherapies for Life®, and My Access® are registered trademarks of CSL Behring LLC. My SourceSM, CSL Behring AssuranceSM, and CSL Behring Patient Assistance ProgramSM are service marks of CSL Behring LLC. Mix2Vial® is a registered trademark of Medimop Medical Projects Ltd.

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