



Important Information Regarding the Availability of Helixate® FS, Antihemophilic Factor (Recombinant)

What this means for your patients

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

CSL Behring
Biotherapies for Life®

Helixate® FS, Antihemophilic Factor (Recombinant), will no longer be manufactured—and here's what your patients need to know

We recognize that Helixate FS has been an important part of your patients' lives. It was with a great deal of consideration that the decision was made to no longer manufacture this product. We created this guide to answer any questions you may have so that you can appropriately advise your patients on their next steps.



How long will Helixate FS be available?

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.



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



Will Helixate FS continue to be covered by insurance plans through 2017?

Your CSL Behring Representative will communicate any Helixate FS coverage or access changes.

Has CSL Behring communicated with my patients about Helixate FS availability?

We have provided a variety of resources regarding the availability of Helixate FS to patients currently taking Helixate FS. In addition to a letter notifying them of the December 2017 date, expected product availability, and a guide that provides additional details, we have also encouraged them to speak with you, their healthcare provider, when considering their next step in hemophilia A therapy. We have also let them know that they can contact their My SourceSM Care Coordinator for help finding answers to any other questions they may have.

Why is Helixate FS being phased out?

As a patient-focused company, CSL Behring strives to create innovative therapies for the hemophilia community. That's why we've put our resources into developing long-lasting AFSTYLA[®], Antihemophilic Factor (Recombinant), Single Chain, a next-generation Factor VIII therapy.

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Consider switching patients to AFSTYLA

? What is AFSTYLA?

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 all studied populations regardless of dosing regimen.

Contact your CSL Behring Representative to learn more about AFSTYLA.

^{*}FDA-approved for dosing 2 or 3 times a week.

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



? Are Helixate® FS, Antihemophilic Factor (Recombinant), and AFSTYLA derived from the same molecule?

No. AFSTYLA is a unique, next-generation product with a novel single-chain design. It is not a derivative of an existing product.

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



Are there patient support programs available for AFSTYLA, as there are for Helixate FS?

Yes. In fact, all the support services your patients have come to rely on and trust with Helixate FS will remain in place for people taking AFSTYLA. Services[‡] include:

- **My Access[®]**—the co-pay program that provides up to \$12,000 of out-of-pocket coverage to covered patients
- **CSL Behring AssuranceSM Program**—helps make product available in case of a lapse in insurance coverage
- **My SourceSM Care Coordinator**—at hand to help your patients navigate the insurance process and answer any questions they may have

Talk to your CSL Behring Representative or call My Source at 1-800-676-4266, Monday to Friday, 8 AM to 8 PM ET, for more details about the support programs available for your patients.

[‡]Terms and conditions apply.



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CSL Behring helps facilitate a smooth transition

? Will my patients taking Helixate® FS, Antihemophilic Factor (Recombinant), need to learn to use a new reconstitution device if they switch to AFSTYLA®, Antihemophilic Factor (Recombinant), Single Chain?

No. AFSTYLA uses the same Mix2Vial® transfer and reconstitution system that they are familiar and comfortable with using with Helixate FS, so their reconstitution routine can remain consistent.

? Why should I consider switching my patients from Helixate FS to another CSL Behring product, such as AFSTYLA?

In addition to the safety and efficacy profile of AFSTYLA and available support programs described on the previous page, CSL Behring is dedicated and committed to you, your patients, and the bleeding disorders community. Rest assured that with more than 30 years' experience treating bleeding disorders, CSL Behring has put the weight of our rigorous quality standards behind AFSTYLA, as with every therapy we develop. Each step of the manufacturing process reflects that long-standing commitment to quality and safety.



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If I find that AFSTYLA is appropriate for my patients, what's involved in getting them started with AFSTYLA and its support programs?

Once you've determined that AFSTYLA is appropriate for your patient, start your patient on a **free 30-day trial**.

- 1. Fill out** an AFSTYLA Patient Referral form to start the trial, enroll your patient in the AFSTYLA support program, and begin a benefits investigation
- 2. Fax** the completed form to My SourceSM at 1-844-727-2757

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 to Friday, 8 AM to 8 PM ET, for further assistance.



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Important contact information

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

You can speak with your CSL Behring Representative or visit **AFSTYLA.com/hcp** to sign up for updates or explore the clinical data in more detail.

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

Your CSL Behring Representative or a My SourceSM Care Coordinator would be happy to answer further questions regarding Helixate FS availability. You can contact My Source at 1-800-676-4266, Monday to Friday, 8 AM to 8 PM ET.

Our Commitment

CSL Behring has provided Helixate FS to patients for more than two decades. We will continue to bring you the most up-to-date information about Helixate FS and AFSTYLA. If you have additional questions, a variety of resources are available to you:

Contact your
**CSL Behring
Representative**

Visit
AFSTYLA.com/hcp
for more information
and to sign up
for updates

Talk with a
**My Source Care
Coordinator** at
1-800-676-4266,
Monday to Friday,
8 AM to 8 PM ET

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As you **evaluate the next steps** for your patients currently taking Helixate FS, we encourage you to **consider AFSTYLA**

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Important Safety Information for HELIXATE FS

HELIXATE® FS, Antihemophilic Factor (Recombinant), is a recombinant factor VIII indicated for:

- On-demand treatment and control of bleeding episodes in adults and children with hemophilia A
- Perioperative management of bleeding in adults and children with hemophilia A
- Routine prophylaxis to reduce the frequency of bleeding episodes in children with hemophilia A and to reduce the risk of joint damage in children without pre-existing joint damage
- Routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes in adults with hemophilia A

HELIXATE FS is not indicated for the treatment of von Willebrand disease.

HELIXATE FS is contraindicated in patients who have life-threatening hypersensitivity reactions, including anaphylaxis to mouse or hamster protein or other constituents of the product.

Hypersensitivity reactions, including anaphylaxis have been reported with HELIXATE FS. Reported symptoms included facial swelling, flushing, hives, decrease in blood pressure, nausea, rash, restlessness, shortness of breath, tachycardia, tightness of the chest, tingling, urticaria, and vomiting. Discontinue HELIXATE FS if symptoms occur and administer immediate emergency treatment.

Neutralizing antibodies (inhibitors) have been reported following administration of HELIXATE FS. Carefully monitor patients for the development of factor VIII inhibitors, using appropriate clinical observations and laboratory tests. If expected plasma factor VIII activity levels are not attained, or if bleeding is not controlled with an expected dose, perform an assay that measures factor VIII inhibitor concentration.

Hemophilic patients with cardiovascular risk factors or diseases may be at the same risk to develop cardiovascular events as non-hemophilic patients when clotting has been normalized by treatment with factor VIII.

Serious adverse reactions seen with HELIXATE FS are systemic hypersensitivity reactions including bronchospastic reactions and/or hypotension and anaphylaxis, and the development of high-titer inhibitors necessitating alternative treatments to factor VIII.

The most common adverse reactions ($\geq 4\%$) observed in clinical trials were inhibitor formation in previously untreated and minimally treated patients, skin-related hypersensitivity reactions, infusion-site reactions, and central venous access device (CVAD)-associated infections.

Please see accompanying full prescribing information for HELIXATE FS.

Important Safety Information for AFSTYLA

AFSTYLA®, Antihemophilic Factor (Recombinant), Single Chain, is indicated in adults and children with hemophilia A (congenital Factor VIII deficiency) for:

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

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

AFSTYLA is contraindicated in patients who have had life-threatening hypersensitivity reactions to AFSTYLA or its excipients, or to hamster proteins.

AFSTYLA is for intravenous use only. AFSTYLA can be self-administered or administered by a caregiver with training and approval from a healthcare provider or hemophilia treatment center. Higher and/or more frequent dosing may be needed for patients under 12 years of age.

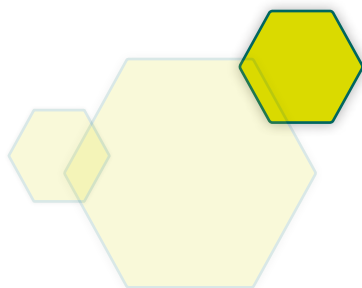
Hypersensitivity reactions, including anaphylaxis, are possible. Advise patients to immediately report symptoms of a hypersensitivity reaction. If symptoms occur, discontinue AFSTYLA and administer appropriate treatment.

Development of Factor VIII (FVIII) neutralizing antibodies (inhibitors) can occur. If expected FVIII activity levels are not attained or bleeding is not controlled with appropriate dose, perform an assay to measure FVIII inhibitor concentration.

Monitor plasma FVIII activity using a chromogenic assay or one-stage clotting assay. **If one-stage clotting assay is used, multiply result by a conversion factor of 2 to determine FVIII activity level.**

The most common adverse reactions reported in clinical trials (>0.5%) were dizziness and hypersensitivity.

Please see accompanying full prescribing information for AFSTYLA.



For your patients on Helixate® FS, Antihemophilic Factor (Recombinant)

What happens once Helixate FS is no longer manufactured?

- Helixate FS will **no longer be manufactured after December 2017**
 - Supply will continue to be **available through early 2019**
- You are encouraged to consider AFSTYLA®, Antihemophilic Factor (Recombinant), Single Chain, a next-generation Factor VIII therapy
 - 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 all studied populations regardless of dosing regimen
- CSL Behring wants to make switching as easy as possible. Patients who switch can:
 - Access the same patient support programs with which they've become familiar
 - Use the same Mix2Vial® reconstitution system they used with Helixate FS

Contact your
**CSL Behring
Representative** or visit
AFSTYLA.com/hcp for
more information and
to sign up
for updates

*FDA-approved for dosing 2 or 3 times a week.

†Annualized spontaneous bleeding rate in clinical trials (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. CSL Behring AssuranceSM and My SourceSM are service marks of CSL Behring LLC. Mix2Vial® is a registered trademark of Medimop Medical Projects Ltd.

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