



Kogenate® FS with BIO-SET® Free Trial Program

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Case Number (For internal processing use only): _____

FOR PATIENTS

Patients: Please check the box that applies to you. Newly diagnosed patient Patient currently receiving FVIII

Patients previously enrolled in the Kogenate FS, antihemophilic factor (recombinant), with BIO-SET needleless reconstitution system Free Trial Program and those currently receiving Kogenate FS with Bio-Set therapy are not eligible to participate.

PATIENT INSTRUCTIONS

Important: In order to become familiar and comfortable with reconstitution, please consult with your healthcare provider prior to using the BIO-SET Patient Practice kit. It is very important that you practice with this kit before using the actual factor. If you need more demonstration kits, please contact the Free Trial Program Manager at the phone number below. Participation in the Kogenate FS with BIO-SET Free Trial Program is not contingent on future treatment purchases.

1. Please fill out the Patient Information section of this form and bring it to your healthcare provider (HCP) to discuss whether **Kogenate FS, antihemophilic factor (recombinant), with BIO-SET needleless reconstitution system**, is right for you.
2. Ask your HCP to fill out the Prescriber and Prescription Information sections of this form.
3. **IMPORTANT: This form must be filled out completely and signed by your HCP or it will not be processed.**
4. Fax or mail the completed form to the fax number/address provided below.
5. For more information, please call 1-866-329-3449.
6. Your free product will be sent to **you** at the address you specify below.

PATIENT INFORMATION

Patient Name: _____ Birth Date: _____

Parent/Guardian Name: _____

Home Phone Number: _____ Alternate Phone Number: _____

Please circle: WORK CELL OTHER

Home Address: _____

City: _____ State: _____ Zip Code: _____

PATIENT-PREFERRED SHIPPING ADDRESS for Kogenate FS with BIO-SET

Ship to: Home Address Address below (Product will be shipped by ACS Inc. and cannot be shipped to your HCP.)

Contact Name: _____

Home Phone Number: _____ Alternate Phone Number: _____

Please circle: WORK CELL OTHER

Shipping Address: (Please include facility name, room #/department, if applicable) _____

Street: _____

Product cannot be shipped to PO boxes

City: _____ State: _____ Zip Code: _____

PATIENT PERMISSION

Important: Your answers to the following questions do not exclude or disqualify you from participation in the Kogenate FS with BIO-SET Free Trial Program.

1. Would you allow an independent, third party to contact you for a follow-up survey about your experience with **Kogenate FS** with BIO-SET? Yes No
2. Please keep me informed about news and announcements related to hemophilia A. Yes No [Privacy Policy](#)
3. Would you like to be contacted by a Bayer Hematology Account Executive? Yes No

Email Address: _____

Patient Signature: _____

FREE TRIAL PROGRAM ENROLLMENT FORM RETURN INSTRUCTIONS

Once the patient and prescriber sections have been completed, please mail or fax the entire form for the **Kogenate FS** with BIO-SET Free Trial Program to:

David Norton
ACS Inc. - Kogenate FS with BIO-SET Free Trial Program
 6251 Chancellor Drive Ste. 101
 Orlando, Florida 32809
 Phone: 1-866-329-3449
 Fax: 1-866-329-3458

Please complete all pages.

Please see indications and important safety information on page 3.

antihemophilic factor
(recombinant)

with BIO-SET®

needleless reconstitution system

Real Life...Real Protection



Kogenate® FS with BIO-SET® Free Trial Program

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Patient Name: _____

FOR PRESCRIBERS

 Newly diagnosed patient

PRESCRIBER INSTRUCTIONS

1. Please fill out this section of the enrollment form completely, including Prescriber and Prescription Information.
2. Patients are eligible for up to 6 free doses of **Kogenate FS** with BIO-SET through the **Kogenate FS** with BIO-SET Free Trial Program. Total factor VIII product will not exceed 5000 IU.
3. This prescription will be filled and shipped directly to the caregiver. Product cannot be shipped to PO boxes.
4. Sign and date the Prescriber Authorization and Release.
5. Fax both sides of the completed form to 1-866-329-3458.
6. For more information, please call 1-866-329-3449.

PRESCRIPTION INFORMATION

Diagnosis: 286.0 Congenital Factor VIII disorder

Patient weight: ____ kg ____ lb Patient FVIII: ____%

Target FVIII activity level desired: ____%

Total **Kogenate FS** IU required for 1 dose: _____

(**Kogenate FS** vial potency will be determined by the fulfilling pharmacy. Patients will receive enough vials to equal 6 doses, not to exceed 5,000 IU total for new patients and not to exceed 20,000 IU total for previously treated patients.)

Special Instructions:

Authorized refills = zero. *The patient must obtain a refill prescription for **Kogenate FS** with BIO-SET for future use.*

PRESCRIBER INFORMATION

Prescriber Name: _____

Facility Name/Office Contact: _____

License # (required by law): _____ DEA #: _____

Address: _____

City: _____ State: _____ Zip Code: _____

Phone Number: _____ Fax Number: _____

For indications, important safety information, and dosage and administration, please see the full Prescribing Information at www.kogenatefs.com/prescribing-information.jsp.

PRESCRIBER AUTHORIZATION AND RELEASE

By signing below, I certify that:

- a. The above therapy is medically necessary.
- b. I have received the necessary authorization to release the above-referenced information and other protected health information (as defined in the Health Insurance Portability and Accountability Act of 1996 [HIPAA]) to Bayer's **Kogenate FS** with BIO-SET Free Trial Program, managed by ACS, and the contracted dispensing pharmacy or other contractors for the purpose of assisting in initiating or continuing therapy, reporting data to Bayer and ACS and/or the evaluation of the patient's eligibility for Bayer's **Kogenate FS** with BIO-SET Free Trial Program.
- c. I appoint ACS as my agent solely to convey on my behalf to the pharmacy chosen by the above-named patient the prescription described herein.
- d. I agree that the medication provided by Bayer through this program is complimentary and that I will not resell or bill any third party, including any federal and state health care programs, for any product provided through this trial prescription program.
- e. I certify that this patient is not currently receiving therapy with **Kogenate FS** with BIO-SET.

Prescriber Signature: _____ Date: _____

 Patient currently receiving FVIII

Patients previously enrolled in the Kogenate FS, antihemophilic factor (recombinant), with BIO-SET needless reconstitution system Free Trial Program and those currently receiving Kogenate FS with Bio-Set therapy are not eligible to participate.

PRESCRIBER INSTRUCTIONS

1. Please fill out this section of the enrollment form completely, including verification of patient training on BIO-SET and the Prescriber and Prescription Information.
2. Patients are eligible for up to 6 free doses of **Kogenate FS** with BIO-SET through the **Kogenate FS** with BIO-SET Free Trial Program. Total factor VIII product will not exceed 20,000 IU.
3. This prescription will be filled and shipped to the address specified by the patient on the reverse side of this form. Product cannot be shipped to PO boxes.
4. The patient must be trained on how to use BIO-SET before receiving the free product trial of **Kogenate FS** with BIO-SET. Please include the training date and authorize with your signature. _____
5. Sign and date the Prescriber Authorization and Release.
6. Fax both sides of the completed form to 1-866-329-3458.
7. For more information, please call 1-866-329-3449.



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■ INDICATIONS

Kogenate® FS, antihemophilic factor (recombinant), is a recombinant factor VIII treatment indicated for the control and prevention of bleeding episodes and peri-operative management in adults and children (0-16 years) with hemophilia A. **Kogenate® FS** is also indicated for routine prophylaxis to reduce the frequency of bleeding episodes and the risk of joint damage in children with hemophilia A with no preexisting joint damage.

■ IMPORTANT SAFETY INFORMATION

The most serious adverse reactions are systemic hypersensitivity reactions and the development of high-titer inhibitors necessitating alternative treatments to AHF. The most common adverse reactions observed in clinical trials were inhibitor formation in previously untreated or minimally treated patients, skin-associated hypersensitivity reactions, infusion site reactions, and central venous access device (CVAD) line-associated infections.

Kogenate® FS is contraindicated in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including mouse or hamster proteins.

For important risk and use information, please see the full Prescribing Information at www.kogenatefs.com/prescribing-information.jsp.

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.



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