



### Selected Important Safety Information

- You should not use JIVI, KOVALTRY, or KOGENATE® FS ANTIHEMOPHILIC FACTOR (RECOMBINANT) if you are allergic to rodents (like mice and hamsters) or any ingredients of JIVI, KOVALTRY or KOGENATE FS.

Continue reading full Indications and Important Safety Information on the next page.

### Subject: Kogenate FS Discontinuation

Dear Kogenate FS Patients, Caregivers and Healthcare Providers,

Bayer is proud of its legacy in serving the hemophilia A community with its family of rFVIII products, which includes Kogenate FS, Kovaltry and Jivi. Kogenate FS has been used by patients since its approval in 1993, while Kovaltry (2016 approval) and Jivi (for patients 12 and older, 2018 approval) are more recent additions to the Bayer hemophilia A family.

Recognizing the growing shift in patient use away from older standard half-life rFVIII products, such as Kogenate FS, towards more recent standard and extended half-life rFVIII products, such as Kovaltry and Jivi, Bayer has made the decision to discontinue Kogenate FS. Keeping the needs of patients, caregivers and healthcare providers in mind, Bayer has carefully considered that you will need sufficient time to consider and make decisions about your next treatment. The timing of discontinuation will vary by Kogenate FS vial size. Customer demand may lead to depletion of the larger vial sizes of Kogenate FS during the fall of 2022. Remaining Kogenate FS vial sizes are anticipated to be available into 2023.

Kovaltry and Jivi are available to meet the needs of patients currently taking Kogenate FS.

- **All children, adolescent, and adult patients currently taking Kogenate FS who would like a rFVIII product with similarities to Kogenate FS should talk to their healthcare provider about transitioning to Kovaltry.** Kovaltry also offers patients currently on Kogenate FS the opportunity to stay on the same dose and frequency.
- **All adult and adolescent patients (12 and older) currently taking Kogenate FS who are interested in an extended half-life (EHL) product should talk to their healthcare provider about transitioning to Jivi.** Jivi has a twice-weekly starting dose and, based on bleeding episodes, the potential to step up to every 5 days dosing and fine tune. More patients taking factor VIII treatments have transitioned to Jivi than to any other EHL product in 2020 and 2021\*.
- **Both Kovaltry and Jivi use the same Vial Adapter reconstitution device as Kogenate FS and offer the same comprehensive patient support services through Access Services by Bayer™.**

It is important for Kogenate FS patients to work with their healthcare provider as they transition products.

Bayer has developed a variety of resources to help as Kogenate FS patients, caregivers, and healthcare providers consider a transition to Kovaltry or Jivi. These include:

- Stories from Kogenate FS patients who have already transitioned to Kovaltry or Jivi (available on [explore.bayer.com](https://www.explore.bayer.com))
- Our Access Services by Bayer™ patient support programs. Through our Free Trial Program, Kogenate FS patients who would like to try Kovaltry or Jivi can receive 1 month of free product, regardless of insurance type or status†. Also, through our \$0 Co-Pay Program, most commercially insured Kogenate FS patients who transition to Kovaltry or Jivi can receive either product for as little as \$0 per prescription, regardless of income‡. Both Kovaltry and Jivi are covered on 99% of commercial, Medicaid and Medicare Advantage plans nationally§.
- A dedicated Kogenate FS Hotline. Patients, caregivers and healthcare providers can call 1-833-40-BAYER, 8:30 a.m. – 8:00 p.m. ET, Monday – Friday
- Our patient website ([explore.bayer.com](https://www.explore.bayer.com)) and healthcare provider website ([discover.bayer.com](https://www.discover.bayer.com)), which include the following information: (1) A Transition Guide, (2) Frequently Asked Questions, (3) Efficacy and safety data from Kovaltry and Jivi clinical studies, including data on patients who transitioned from Kogenate FS, (4) Contact information for your Bayer Representative, and (5) Full details on all of our patient support programs.

We very much value the opportunity to continue to meet your needs. We sincerely hope that Kogenate FS patients, caregivers, and healthcare providers will discuss whether remaining in the Bayer family by transitioning to Kovaltry or Jivi may be the right choice.

For additional important risk and use information, please see the Full Prescribing information for [KOGENATE FS](#), [KOVALTRY](#), or [JIVI](#).



## **Indications and Important Safety Information for JIVI, KOVALTRY, and KOGENATE® FS ANTIHEMOPHILIC FACTOR (RECOMBINANT)**

JIVI, KOVALTRY, and KOGENATE FS are injectable medicines used to replace clotting factor (Factor VIII or antihemophilic factor) that is missing in people with hemophilia A.

### **Indication For JIVI**

JIVI is used to treat and control bleeding in previously treated adults and adolescents (12 years of age and older) with hemophilia A. Your healthcare provider may also give you Jivi when you have surgery. JIVI can reduce the number of bleeding episodes in adults and adolescents with hemophilia A when used regularly (prophylaxis).

JIVI is not for use in children below 12 years of age or in previously untreated patients.

### **Indication For KOVALTRY**

KOVALTRY is used to treat and control bleeding in adults and children with hemophilia A. KOVALTRY can reduce the number of bleeding episodes in adults and children with hemophilia A when used regularly (prophylaxis). Your healthcare provider may give you KOVALTRY when you have surgery.

### **Indication For KOGENATE FS**

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

JIVI, KOVALTRY, and KOGENATE FS are not indicated for the treatment of von Willebrand disease.

### **Important Safety Information About JIVI, KOVALTRY, and KOGENATE FS**

- You should not use JIVI, KOVALTRY, or KOGENATE FS if you are allergic to rodents (like mice and hamsters) or any ingredients in JIVI, KOVALTRY, or KOGENATE FS.
- Tell your healthcare provider about all the medical conditions that you have or had or are at risk of such as heart disease.
- Allergic reactions may occur with JIVI, KOVALTRY, and KOGENATE FS. Call your healthcare provider right away and stop treatment if you get rash or hives, itching, tightness of the chest or throat, dizziness, difficulty breathing, decrease in blood pressure, and nausea.
- Allergic reactions to polyethylene glycol (PEG), a component of JIVI, are possible.
- Your body can also make antibodies, called "inhibitors," against JIVI, KOVALTRY, and KOGENATE FS, which may stop JIVI, KOVALTRY, and KOGENATE FS from working properly. Consult your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to Factor VIII.
- If your bleeding is not being controlled with your usual dose of JIVI, KOVALTRY, or KOGENATE FS consult your doctor immediately. You may have developed Factor VIII inhibitors to JIVI, KOVALTRY, or KOGENATE FS. If your bleeding is not being controlled with your usual dose of JIVI you may have developed antibodies to PEG and your doctor may carry out tests to confirm this.
- The common side effects of JIVI are headache, cough, nausea, and fever.
- The common side effects of KOVALTRY are fever, headache, and rash, in addition to inhibitors in patients who were not previously treated or minimally treated with Factor VIII products.
- Other common side effects of KOGENATE FS are local injection site reactions (pain, swelling, irritation at infusion site) and infections from implanted injection device.
- These are not all the possible side effects with JIVI, KOVALTRY, and KOGENATE FS. Tell your healthcare provider about any side effect that bothers you or that does not go away.

Sincerely,

Theresa Natalicchio

Senior Vice President & General Manager, Specialty Franchise

For additional important risk and use information, please see the Full Prescribing information for [KOGENATE FS](#), [KOVALTRY](#), or [JIVI](#).



You are encouraged to report side effects or quality complaints of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

\*Data from 3rd party market research (Q4'2019 – Q4'2021). Patient numbers are projected to the total market level

†Participation in the Free Trial Program is limited to 1 time only per product. The Free Trial Program includes 1 month supply up to a maximum of 40,000 IU. The Free Trial Program for Jivi is available to patients 12 years of age and older. Bayer reserves the right to rescind, revoke, or amend this offer without notice at any time. The medication provided through this program is at no cost to the patient and is not contingent on future use of this medication. Reselling or billing any third party for free product provided by this program is prohibited by law.

‡ Patients who are enrolled in any type of government insurance are not eligible. Bayer reserves the right to rescind, revoke, or amend this offer without notice at any time. Co-pay program support is available for up to 1 year. Can include any out-of-pocket prescription costs, such as co-pay and co-insurance. Up to \$20,000 in co-pay assistance available per year. Eligible patients will be auto-enrolled every January.

§ Formulary status is believed to be accurate as of January 1, 2022 but cannot be guaranteed. Formulary status for national plans may not reflect plan variation at the local level. Lower co-pay costs do not necessarily reflect a cost advantage in the outcome of the condition treated because there are other variables that affect relative cost. Formulary status does not imply a comparison of efficacy, safety, or dosing. Jivi coverage includes pharmacy and medical lives across commercial (99%), fee-for-service Medicaid (100%), Managed Medicaid (100%) & Medicare Advantage (100%). Percentage represents the coverage within the book of business. n=1,518, 51, 369, 748. Kovaltry coverage includes pharmacy and medical lives across commercial (99%), fee-for-service Medicaid (100%), Managed Medicaid (100%) & Medicare Advantage (100%). Percentage represents the plan coverage within the book of business: n=1,798; 51; 410; 1,112.

For additional important risk and use information, please see the Full Prescribing information for [KOGENATE® FS ANTIHEMOPHILIC FACTOR \(RECOMBINANT\)](#), [KOVALTRY](#), or [JIVI](#).