



# Kogenate<sup>®</sup> FS On-Demand Patients

Are you a Kogenate<sup>®</sup> FS On-Demand patient looking to transition to a different product?  
**Learn more** about recent Bayer offerings.

JIVI<sup>®</sup>, KOVALTRY<sup>®</sup>, 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<sup>®</sup>

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 KOGENATE<sup>®</sup> 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.

#### SELECTED IMPORTANT SAFETY INFORMATION ABOUT KOGENATE FS, KOVALTRY, AND JIVI

- 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.

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



## Kogenate® FS, Kovaltry®, and Jivi® at a glance

	Kogenate FS <sup>1</sup>	Kovaltry <sup>2</sup>	Jivi <sup>3</sup>
<b>FDA Approval</b>	1993	2016	2018
<b>Who It's For (indicated age groups)</b>	← Pediatric, adolescent and adult patients (0 - 65+) →		Adolescent and adult patients (12 - 65+) Not indicated for children under 12 years of age or in previously untreated patients
<b>Half-Life</b>	← Standard half-life (SHL) →		Extended half-life (EHL)
<b>Reconstitution System</b>	← Vial Adapter reconstitution device →		
	← 25-gauge butterfly needle and pre-filled diluent syringe →		
<b>Cell Line</b>	← Same type of cell line →		

1. Kogenate Prescribing Information. Bayer HealthCare LLC, Whippany, NJ. 2. Kovaltry Prescribing Information. Bayer HealthCare LLC, Whippany, NJ; 2021. 3. Jivi Prescribing Information. Bayer HealthCare LLC, Whippany, NJ; 2018.

### 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.

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

### SELECTED IMPORTANT SAFETY INFORMATION ABOUT JIVI, KOVALTRY, AND KOGENATE FS

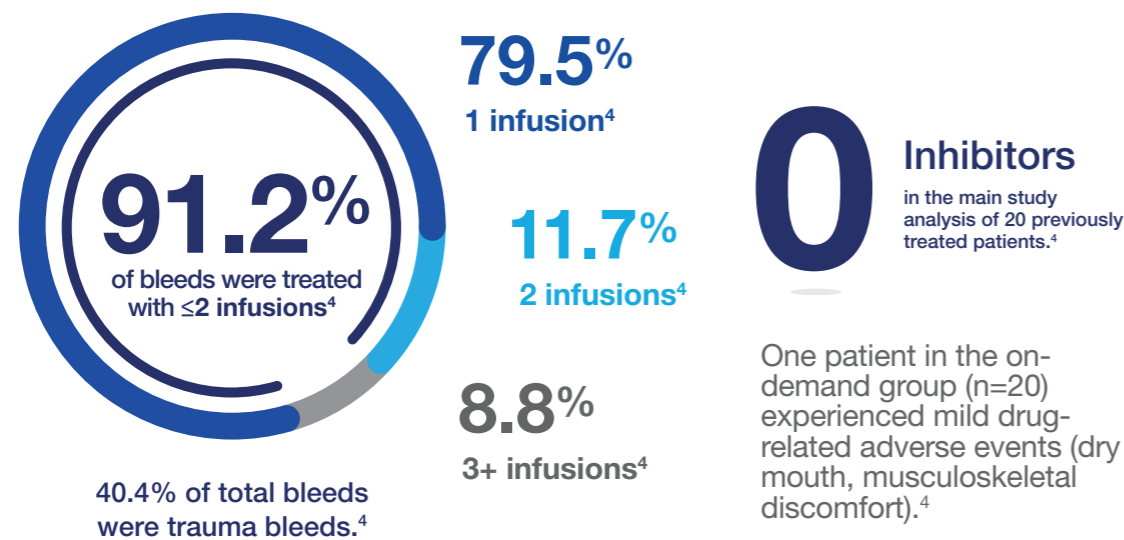
- Tell your healthcare provider about all the medical conditions that you have or had or are at risk of such as heart disease.
- Allergic reactions may occur with JIVI, KOVALTRY, and KOGENATE FS. Call your healthcare provider right away and stop treatment if you get rash or hives, itching, tightness 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.

Please see additional Important Safety Information throughout and the accompanying full Prescribing Information for [JIVI](#), [KOVALTRY](#), and [KOGENATE FS](#).

**Jivi®: Efficacy and safety for on-demand treatment in adolescents and adults, including those who transitioned from Kogenate® FS<sup>3,4,5</sup>**

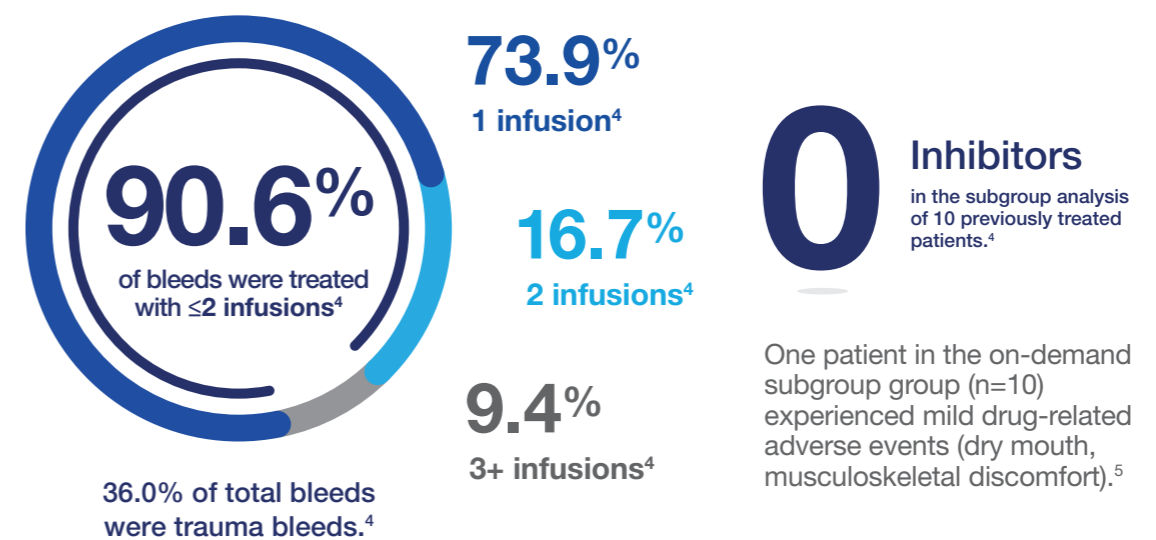
**Jivi Clinical Study (20 patients)**

The safety and efficacy of Jivi® for on-demand treatment in adolescent and adult (12 to 65 years of age) previously treated patients (PTPs) was evaluated for 36 weeks.<sup>3,4</sup>



**10 Kogenate FS on-demand patients transitioned to Jivi on-demand as part of the clinical study.<sup>4</sup>**

**In an analysis of the clinical study data completed after the study ended, it was determined that in Kogenate FS patients who transitioned to Jivi:**



The on-demand arm in the Jivi clinical study and the subgroup analysis both included patients with Hepatitis B, Hepatitis C, and HIV.<sup>5</sup>

3. Jivi Prescribing Information. Bayer HealthCare LLC, Whippany, NJ; 2018. 4. Data on file. Protect VIII (13024) prior OD Kogenate FS/Helixate FS Cohort Descriptive Analysis. Bayer Healthcare LLC, Whippany, NJ. 5. Data on file. Jivi Protect FVIII (13024) Subgroup- prior Kogenate FS/Helixate FS Cohort. Bayer Healthcare LLC, Whippany, NJ.

**SELECTED IMPORTANT SAFETY INFORMATION ABOUT KOGENATE FS AND JIVI**

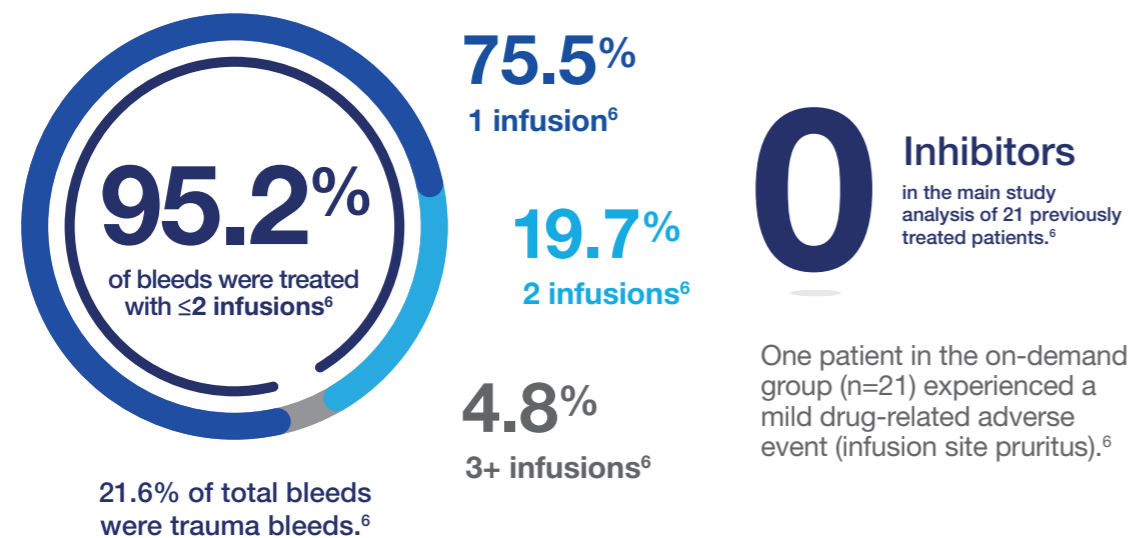
- Your body can also make antibodies, called “inhibitors,” against JIVI, KOVALTRY, and KOGENATE FS, which may stop JIVI, KOVALTRY, and KOGENATE FS from working properly. Consult your healthcare provider to make sure you are carefully monitored with blood tests for the development of inhibitors to Factor 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.
- 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.

Please see additional Important Safety Information throughout and the accompanying full Prescribing Information for [JIVI](#), [KOVALTRY®](#) ANTIHEMOPHILIC FACTOR (RECOMBINANT), and [KOGENATE FS](#).

**Kovaltry®: Efficacy and safety for on-demand treatment in adolescents and adults, including those who transitioned from Kogenate® FS<sup>2,6,7</sup>**

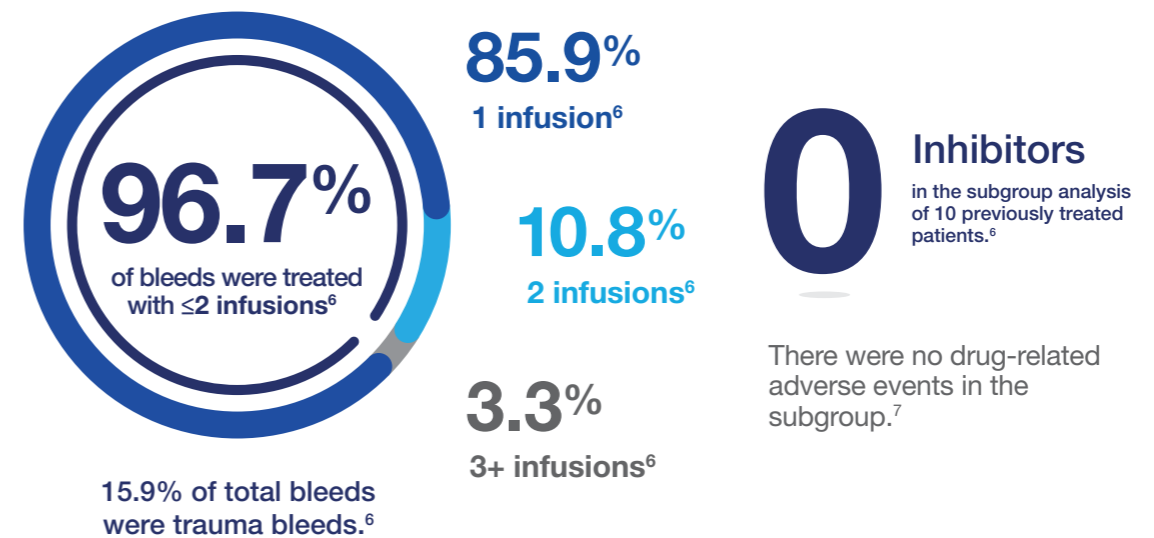
**Kovaltry Clinical Study (21 patients)**

The safety and efficacy of Kovaltry® for on-demand treatment in adolescent and adult (12 to 65 years of age) previously treated patients (PTPs) was evaluated for 12 months.<sup>2,6</sup>



10 Kogenate FS on-demand patients transitioned to Kovaltry on-demand as part of the clinical study.<sup>6</sup>

In an analysis of the clinical study data completed after the study ended, it was determined that in Kogenate FS patients who transitioned to Kovaltry:



The on-demand arm in the Kovaltry clinical study and the subgroup analysis both included patients with Hepatitis B, Hepatitis C, and HIV.<sup>6</sup>

2. Kovaltry Prescribing Information. Bayer HealthCare LLC, Whippany, NJ; 2021. 6. Data on file. Leopold II (14319) prior OD Kogenate FS/Helixate FS Cohort - Descriptive analysis. Bayer Healthcare LLC, Whippany, NJ. 7. Data on file. Leopold II (14319) prior OD Kogenate FS/Helixate FS Cohort. Bayer Healthcare LLC, Whippany, NJ.

**SELECTED IMPORTANT SAFETY INFORMATION ABOUT JIVI®, KOVALTRY, AND KOGENATE FS**

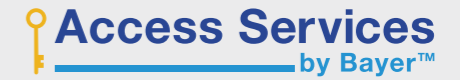
- The common side effects of JIVI are headache, cough, nausea, and fever.
- The common side effects of KOVALTRY are fever, headache, and rash, in addition to inhibitors in patients who were not previously treated or minimally treated with Factor VIII products.
- Other common side effects of KOGENATE 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.

Please see additional Important Safety Information throughout and the accompanying full Prescribing Information for [JIVI ANTIHEMOPHILIC FACTOR \(RECOMBINANT\) PEGYLATED-AUCL](#), [KOVALTRY](#), and [KOGENATE FS](#).



# Bayer is committed to helping you with insurance, financial and affordability challenges

Take advantage of all that Access Services by Bayer can offer, including:



<p><b>Patient Loyalty Program<sup>†§¶</sup></b></p> <p><b>Bayer is committed to helping you start and stay on therapy regardless of changes in your commercial health insurance coverage status.</b></p> <p>Eligible patients can receive Kogenate<sup>®</sup> FS, Kovaltry<sup>®</sup> or Jivi<sup>®</sup> at no cost if you experience gaps or changes with insurance coverage.</p>	<p><b>Free Trial Program<sup>§</sup></b></p> <p>Patients new to Kovaltry or Jivi can receive <b>1 month of free therapy.</b></p> <ul style="list-style-type: none"> <li>• The selected product is delivered to your home.</li> <li>• Any patient new to Kovaltry or Jivi is able to participate, regardless of insurance type or status.</li> </ul>
<p><b>\$0 Product Co-Pay Program<sup>†</sup></b></p> <p>Most commercially insured patients can receive Kovaltry or Jivi for as little as \$0 per prescription, regardless of income. <b>(Up to \$12,000 in out-of-pocket cost assistance available per year.)</b></p> <p><b>Assistance is awarded per patient.</b> Multiple members of the same household can apply.</p> <p>Call <b>1-647-245-5619</b> or visit <a href="http://copaysupport.bayer.com">copaysupport.bayer.com</a> to get started saving today!</p>	<p><b>Jivi Reimbursement for Lab Testing<sup>†</sup></b></p> <p>You may be able to receive up to \$250 per year to offset out-of-pocket costs for laboratory tests for Jivi.</p> <p><b>Live Helpline Support</b></p> <p>Consult with an <b>insurance expert</b></p> <p><b>Live helpline</b> support from 8:00 AM to 8:00 PM ET, Monday - Friday</p> <p><b>Multiple languages</b>, including Spanish, are available</p>

## Jivi and Kovaltry are covered for 99% of patients nationally.<sup>¶#</sup>

\*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.

†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.

‡Participation in the Jivi or Kovaltry Free Trial Program is limited to 1 time only per product (patients currently using Jivi or Kovaltry are not eligible for a Free Trial of their current 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.

¶Formulary status is believed to be accurate as of March 1, 2021 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%), and Managed Medicaid (100%); it does not include Medicare (48%). Kovaltry coverage includes pharmacy and medical lives across commercial (99%), fee-for-service Medicaid (100%), and Managed Medicaid (100%); it does not include Medicare (49%). Percentage represents the coverage within the book of business. n=1,635, 51, 366.

### SELECTED IMPORTANT SAFETY INFORMATION ABOUT JIVI, KOVALTRY, AND KOGENATE FS

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



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For more information, visit  
**[explore.bayer.com](https://www.explore.bayer.com)**

And speak with your doctor about Jivi<sup>®</sup> or Kovaltry<sup>®</sup>

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

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