

August 9, 2019



**Update on the Recall of Two Lots of Kogenate® FS antihemophilic factor (recombinant)
#27118RK and #27119CG**

Dear Hemophilia A Patients, Caregivers and Healthcare Providers,

As part of our commitment to patient safety, we understand that it is imperative for our quality practices and manufacturing protocols to be maintained at the highest level at all times. In the case of the recent voluntary recall of two lots of Kogenate FS that did not happen. We truly apologize for our error and the concerns it has caused. We know we must do better.

Since confirming the mislabeling issue and reporting it to the FDA, we have conducted an extensive review of the situation to fully understand how it happened and what measures need to be implemented to prevent a similar situation from occurring again. As part of our effort to rebuild trust, we want to take this opportunity to share additional information about the cause of the mislabeling and our plans to take corrective actions.

How did the mislabeling occur?

Based on the evidence reviewed during our investigation, it has been determined that the mislabeling was due to human error.

- As is standard practice, prior to being labelled, the vials of Kogenate FS 2000 IU were kept in a wheeled storage cabinet and maintained in a cold storage room at our manufacturing site in Berkeley, California. Each individual vial has a batch identifier number on its aluminum cap, and the storage cabinets are tagged to identify its content.
- Also kept in the same cold storage area was a cabinet of Jivi® antihemophilic factor (recombinant) PEGylated-aucl 3000 IU. Each of its vials also has a unique batch identifier on its aluminum cap, and the storage cabinets are also tagged to identify its content.
- While this Jivi batch had expired in August 2018, it was being maintained in order to conduct ongoing stability testing. It is common that after some batches expire we continue to hold them to conduct tests to help further our understanding of the product. This Jivi batch met extended stability specifications as of April 2019. In addition, all quality attributes, including potency and purity of this Jivi product, continued to meet product specifications as of July 19, 2019.
- When an operator transported the cabinets of Kogenate FS 2000 IU to the vial labeling area, the Jivi 3000 IU cabinet was transported as well, although it should not have been. The result was that the Jivi 3000 IU vials were incorrectly included along with Kogenate FS 2000 IU vials during the Kogenate FS labeling process.

Vial identity is procedurally verified and documented by the operator who performs the labeling task. It is also subject to a separate verifier, and thereafter, independently checked by a quality inspector. In this situation, these controls failed to prevent the mislabeling.

The issue was subsequently identified during a routine inventory check, which led to an investigation and the recall.

What are we doing to prevent this issue from happening again?

Our examination looked at all areas in the process that may be prone to human error. We have since established corrective action plans to strengthen our processes and work environment, as well as create engineering and electronic controls to significantly reduce the potential for human error.

The following highlights several of our key corrective actions steps:

1. **Separate Storage Areas** – Expired vials are now stored in a separate building from where in-process vials are stored and labeled.
2. **Technology Controls** – Additional engineering and electronic controls, such as smart locks tied to specific batch numbers have been implemented. Bar code readers and scanners are in the process of being implemented.
3. **Updated Procedures and Training** – We conducted an extensive review of our procedures and protocols and have implemented changes to include more detailed procedures, instructions and documentation for the packaging and labeling operations. Among these changes, we have implemented stronger physical separation between product batches and product-specific color coding of batch labels.

Next Steps

The Bayer Call Center (1-888-84-BAYER (1-888-842-2937) is continuing to be available to answer any questions about the recall. Importantly, if patients have suffered out of pocket financial losses due to this recall, they should speak with our Call Center, and we will review these on a case by case basis and offer individuals remuneration for their losses.

We hope the information in this letter has been useful and provides transparency into this matter. By choosing our products, we recognize you put tremendous trust in Bayer. Be assured, we are working hard to put plans in place to prevent this issue from occurring again. Should you have any additional questions, I encourage you to reach out to our Bayer Call Center (1-888-84-BAYER).

Kind regards,



Paul Bedard
Senior Vice President, Specialty Franchise

Kogenate® FS antihemophilic factor (recombinant)

Indications and Important Safety Information

Indications

Kogenate® 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.

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.

Kogenate FS is not used to treat von Willebrand disease.

Important Safety Information

You should not use Kogenate FS if you are allergic to rodents (like mice and hamsters) or are allergic to any ingredients in Kogenate 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 Kogenate 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, called “inhibitors,” against Kogenate FS, which may stop Kogenate 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 Kogenate 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 Kogenate FS.

For important risk and use information, please see [full prescribing information](#).

Jivi® antihemophilic factor (recombinant) PEGylated-aucl

Indications and Important Safety Information

INDICATIONS

- Jivi is an injectable medicine used to replace clotting factor (Factor VIII or antihemophilic factor) that is missing in people with hemophilia A.
- 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.
- Jivi is not used to treat von Willebrand disease.

IMPORTANT SAFETY INFORMATION

- You should not use Jivi if you are allergic to rodents (like mice and hamsters) or to any ingredients in Jivi.
- Tell your healthcare provider about all of your medical conditions that you have or had.
- Tell your healthcare provider if you have been told that you have inhibitors to Factor VIII.
- Allergic reactions may occur with Jivi. Call your healthcare provider right away and stop treatment if you get tightness of the chest or throat, dizziness, decrease in blood pressure, or nausea.
- Allergic reactions to polyethylene glycol (PEG), a component of Jivi, are possible.
- Your body can also make antibodies, called “inhibitors,” against Jivi, which may stop Jivi 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, consult your doctor immediately. You may have developed Factor VIII inhibitors or 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.
- These are not all the possible side effects with Jivi. Tell your healthcare provider about any side effect that bothers you or that does not go away.

For additional important risk and use information, please see full [Prescribing Information](#).