IMPORTANT DRUG INFORMATION UPDATE

July 19, 2019

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Kogenate® FS Antihemophilic Factor (Recombinant)

Recall of Two Lots of 2000 IU vials (Lot # 27118RK and 27119CG)

Dear Healthcare Professional,

Bayer, in coordination with the Food and Drug Administration, is implementing a voluntary recall in the United States of two lots of hemophilia A drug Kogenate® FS Antihemophilic Factor (Recombinant) 2000 IU vials (lot # 27118RK and 27119CG). In these two released lots of Kogenate® FS, approximately 990 vials contain Jivi®, antihemophilic factor (recombinant) PEGylated-aucl, 3000 IU, erroneously mislabelled as Kogenate® FS Antihemophilic Factor (Recombinant) 2000 IU. Additionally, the Jivi® drug product contained in the mislabelled vials has passed its expiration date.

All distributors, pharmacies, HCPs and patients are alerted to discontinue the use of affected product. Distributors, pharmacies and HCPs are directed to contact the Bayer Recall Coordinator, Inmar, at 855-707-7518 to arrange for return of the product. Patients in possession of vials from the affected lot numbers should immediately stop using the product and contact their physician. In addition, patients should contact their pharmacy to return the affected product.

Any side effects or complications should promptly be reported to Bayer at 1-888-84-BAYER (1-888-842-2937).

Summary

- Kogenate® FS Antihemophilic Factor (Recombinant) is indicated for use in children, and adults with hemophilia A (congenital Factor VIII deficiency), for on-demand treatment and control of bleeding episodes and perioperative management of bleeding. It is additionally indicated for routine prophylaxis in children with hemophilia A and to reduce the risk of joint damage in children without pre-existing joint damage. Kogenate® FS is also indicated for routine prophylaxis to reduce the frequency of bleeding episodes in adults with hemophilia A. Kogenate® FS is not indicated for the treatment of von Willebrand disease.

- Jivi®, antihemophilic factor (recombinant), PEGylated-aucl, is a recombinant DNA-derived, Factor VIII concentrate indicated for use in previously treated adults and adolescents (12 years of age and older) with hemophilia A (congenital Factor VIII deficiency) for on-demand treatment and control of bleeding episodes, perioperative

management of bleeding and routine prophylaxis to reduce the frequency of bleeding episodes. Jivi® is not indicated for use in children < 12 years of age due to a greater risk for hypersensitivity reactions and is not indicated for use in previously untreated patients (PUPs) or for the treatment of von Willebrand disease.

- Bayer Healthcare LLC, Berkeley, CA manufactures recombinant antihemophilic factor products for use within and outside the USA, including Kogenate® FS and Jivi®. In the process of routine quality control, Bayer discovered that a batch of Jivi® 3000 IU expired unlabelled vials were erroneously mislabelled as Kogenate® FS 2000 IU during a production run. Approximately 990 of these vials were distributed only to the US market. The Jivi 3000 IU batch expired in August 2018, while continuing to meet extended stability specifications as of April 2019.

- The affected lots, distributed from Feb 5, 2019 to July 15, 2019 from Bayer's distribution sites in Berkeley, CA and Shawnee, KS, are listed below

Product name	NDC Number	Product Code	Lot Number	Expiration Date
Kogenate FS Antihemophilic Factor (Recombinant) 2000 IU	0026-3786-65	DR03	27118RK	06/12/2021
	0026-3786-65	DR03	27119CG	06/12/2021

- Bayer has voluntarily recalled both lots in the interest of patient safety, to ensure that any potentially impacted product is removed from pharmacy shelves and that patients and their health providers are alerted.

- Importantly, vials of Kogenate® FS that are not associated with the affected lot numbers (27118RK and 27119CG) are not impacted and can continue to be used. There are no lots of Jivi® antihemophilic factor (recombinant), PEGylated-aucl or Kovaltry® antihemophilic factor (recombinant) product affected by this recall.

Assessment

- Jivi® is not indicated for use in previously untreated patients, and in children < 12 years of age due to potential clinical immune response to polyethylene glycol (PEG) presenting as hypersensitivity reactions and/or loss of efficacy which could potentially occur within the first 4 administrations.

- Jivi® has a longer half-life relative to Kogenate® FS. The more frequent dosing schedule for Kogenate® FS and the higher dose per vial (3,000 IU vs. 2,000 IU) may contribute to increased plasma levels of factor VIII. Elevated plasma levels of factor VIII may be associated with an increased risk of thrombosis, primarily in patients with vascular disease.

- The efficacy of the mislabelled Kogenate® FS vials may be compromised due to the fact that the product (Jivi®) was beyond the expiration date, although the product has met stability specifications as of April 2019.

- To date, one patient who may have received the suspect vials has reported a myocardial infarction. We are actively monitoring for any complaints or adverse event reports that may be related to this recall.

Healthcare Provider actions

If you have patients that have affected product, please advise them to discontinue the use of the affected product and contact the pharmacy where they obtained their product.

If you have any questions about the recall process, please contact the Bayer Recall Coordinator, Inmar, at 855-707-7518.

Reporting adverse drug reactions

Any complications or side effects with the use of Kogenate® FS should be reported to Bayer Medical Communications at 1-888-84-BAYER (1-888-842-2937). Healthcare providers and patients are encouraged to report negative side effects or quality complaints of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please refer to accompanying full Prescribing Information for Kogenate® FS and Jivi® for complete indications and important risks.

For any questions, please contact Bayer medical communications at: 1-888-84-BAYER (1-888-842-2937).

With kind regards,

Aleksandra Vlajnic, MD, MBA
Vice President, US Medical Affairs
Bayer HealthCare Pharmaceuticals, Inc.

Enclosure(s): Kogenate® FS and Jivi® Full Prescribing Information