ASD Healthcare
AmerisourceBergen

M-F 7:00AM to 6:00PM CST
asdhealthcare.com
800.746.6273
800.547.9413

July 22, 2019

Urgent: Bayer Issues a Voluntary Recall of Two Lots of Kogenate® FS antihemophilic factor (recombinant) 2000 IU.

Dear ASD Healthcare Customer:

Bayer is initiating a voluntary recall of two lots of Kogenate FS antihemophilic factor (recombinant) 2000 IU. The affected lot information is listed below.

This product is being voluntarily recalled because some vials from these two lots that were labeled as Kogenate FS actually contain FVIII hemophilia A treatment, Jivi® antihemophilic factor (recombinant) PEGylated-aucl 3000 IU. The affected lots were distributed from February 5, 2019 to July 15, 2019. Therefore, due to patient safety concerns, Bayer is recalling Kogenate FS antihemophilic factor (recombinant) 2000 IU.

Bayer provided the affected lot information below:

Product Description	NDC Number	Lot Number	Expiration Date
Kogenate FS antihemophilic factor (recombinant) 2000 IU	0026-3786-65	27118RK	6/12/2021
	0026-3786-65	27119CG	6/12/2021

To reduce any risk, we ask for your cooperation in taking the following action:

- Please examine your inventory immediately to determine if you have any impacted product in stock and quarantine the affected product.
- **Immediately notify your individual patients** with instructions to coordinate the return and replacement of their affected product.
- **Use the Request a Return tool to get started. Return product to ASD Healthcare's warehouse (address listed below).**

  Warehouse Supervisor
  ASD Healthcare
  345 International Blvd, #400A
  Brooks, KY 40109

For the full recall notice, please view the attached document on the following pages.

If you have any questions or concerns, please contact ASD Healthcare's customer service at **800.746.6273.**

IMPORTANT: DRUG RECALL
Kogenate® FS antihemophilic factor (recombinant) 2000 IU
Lot 27118RK, Lot 27119CG

July 19, 2019
Dear Kogenate® FS Customer,

Bayer is voluntarily recalling two lots of Kogenate® FS antihemophilic factor (recombinant) 2000 IU vials in the United States to the patient level. Some vials from these two lots that were labeled as Kogenate FS actually contain the FVIII hemophilia A treatment, Jivi® antihemophilic factor (recombinant) PEGylated-aucl 3000 IU. Bayer is working closely with the U.S. Food and Drug Administration to manage the recall and to minimize disruption to supply and inconvenience to patients. The affected lots, distributed from Feb 5, 2019 to July 15, 2019 from our 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 is initiating a patient level voluntary recall. As such, we ask that you please:

- Immediately quarantine inventory of the affected product under your direct control
- Immediately notify your individual patients or customers with instructions to coordinate the return and replacement of their affected product through their specialty pharmacy
- Contact ASD Healthcare for instructions on the return process

Bayer is committed to minimizing any potential disruption in product supply. If you have questions related to replenishment, please call Bayer Customer Service toll free, at 1-888-606-3780 or Email: USHematology@bayer.com.

For other inquiries, please call Bayer Medical Communications at 1-888-84-BAYER (1-888-842-2937.)

Sincerely,

Karin Ann Payne
Bayer US Quality Head