

URGENT DRUG RECALL

July 13, 2020

<u>Product Name/Product size</u>	<u>NDC Number</u>	<u>Product Code</u>	<u>Batch Number</u>	<u>Expiration Date</u>	<u>First Ship Date</u>	<u>Last Ship Date</u>
Fosaprepitant for Injection, 150 mg / vial in a 10 mL vial	63323-972-10	972010	6122760	08/2021	09/30/2019	12/30/2019
			6122761	08/2021	12/30/2019	04/06/2020
			6122762	09/2021	12/02/2019	06/16/2020
			6123883	03/2022	05/20/2020	06/22/2020

Dear Customer/Health Professional:

This letter is to notify you that Fresenius Kabi USA, LLC (“Fresenius Kabi”) is voluntarily recalling the above-mentioned batches of Fosaprepitant for Injection, 150 mg / vial in a 10 mL vial.

This recall is being performed to the user level. Fresenius Kabi has decided to take this action due to the carton label and product insert incorrectly stating the quantity of the excipient edetate disodium (EDTA) as 5.4 mg / vial, rather than the actual amount of 18.8 mg / vial. The investigation reveals that this issue is limited to the product batches indicated above.

Fresenius Kabi USA has not received any reports of adverse events related to this recall. Inconsistency between the labeling in the package insert and carton may pose a risk of misrepresentation of the EDTA content to physicians when treating patients; however, the higher content of EDTA poses little risk, and is an FDA-approved formulation of the product. Therefore, the associated health risk is assessed as low.

You are required to return all product from the above-mentioned batches that you have in your possession. To implement this recall, please do the following:

1. Examine your stock **immediately** to determine if you have any product vials from the affected batches. Quarantine any affected stock. If you are a distributor, immediately notify your customers that have been shipped or may have been shipped this product and direct them to quarantine and discontinue distributing or dispensing the affected batches. Please have them prepare to return the product to Fresenius Kabi (see enclosed information). Your customers may retrieve the recall letter and response form at <https://www.fresenius-kabi.com/us/pharmaceutical-product-updates>.
2. If you have the affected batches available, **immediately quarantine and discontinue distributing, or dispensing** any vials from the batches, and return all vials to Fresenius Kabi, USA, LLC located at 600 Supreme Drive, Bensenville, IL 60106, via FedEx Ground, using the enclosed return goods label and packing slip. A FedEx Ground label can be obtained by checking the box and noting your mailing address on the enclosed Urgent Product Recall Response Form. It will be mailed to you upon receiving your request. A credit memo will be issued covering the quantity of your return to Fresenius Kabi USA, LLC.

PLEASE COMPLETE THE ENCLOSED “URGENT PRODUCT RECALL RESPONSE FORM” AND SEND IT BACK IMMEDIATELY VIA EMAIL TO FK-NARECALLS@FRESENIUS-KABI.COM OR FAX AT 1-708-649-8630.

CONTACT NUMBERS: Use the following contact phone numbers. Hours of operation: Monday through Friday 8:00 am to 5:00 pm CST

<u>Number</u>	<u>Department</u>	<u>Reason to Call</u>
(866) 716-2459	Quality Assurance Department	Information on how to return product
(800) 551-7176	Vigilance or Medical Affairs	For clinical/technical information/Adverse Event (ADE) reporting

This recall is being made with the knowledge of the United States Food and Drug Administration (FDA).

We apologize for any inconvenience this voluntary recall may cause you.

Sincerely,



Melanie Power-Burns
Sr Vice President Quality Assurance

URGENT PRODUCT RECALL RESPONSE FORM

URGENT: DRUG RECALL - Sterile Injectable

July 13, 2020

Please complete and fax to: 1-708-649-8630

To: Fresenius Kabi USA, LLC

Attn:

Quality
Assurance
Department

<u>Product Name/Product size</u>	<u>NDC Number</u>	<u>Product Code</u>	<u>Batch Number</u>	<u>Expiration Date</u>	<u>First Ship Date</u>	<u>Last Ship Date</u>
Fosaprepitant for Injection, 150 mg / vial in a 10 mL vial	63323-972-10	972010	6122760	08/2021	09/30/2019	12/30/2019
			6122761	08/2021	12/30/2019	04/06/2020
			6122762	09/2021	12/02/2019	06/16/2020
			6123883	03/2022	05/20/2020	06/22/2020

1. Examine your inventory **immediately** to determine if you have any product from the above-mentioned batches.
2. If so, **immediately** discontinue distribution or dispensing of the affected batches and return all units to Fresenius Kabi USA, LLC located at 600 Supreme Drive, Bensenville, IL 60106 via FedEx Ground using the enclosed return goods label and packing slip. A credit memo will be issued covering the quantity of your return to Fresenius Kabi USA, LLC.
PLEASE COMPLETE THIS FORM AND SEND IT BACK TO US IMMEDIATELY VIA EMAIL AT FK-NARECALLS@FRESENIUS-KABI.COM OR FAX AT 1-708-649-8630.
3. **PLEASE COMPLETE THIS FORM AND SEND IT BACK TO US IMMEDIATELY VIA EMAIL AT FK-NARECALLS@FRESENIUS-KABI.COM OR FAX AT 1-708-649-8630.**

- We currently do not have units of the batch numbers on hand.
- We are returning _____ vials **OR** _____ trays/cartons
of Labels needed _____
- I have identified contacted direct account customers that have been shipped or may have been shipped this product. Please send FedEx Ground Shipping Labels to the address below.

FROM: Hospital (other): _____

Street Address: _____

City, State, Zip code: _____

Signature: _____

From:

FACILITY:
ADDRESS:
CITY, STATE, ZIP:

Signature _____

Date _____



ATTN: URGENT DRUG RECALL

PACKING SLIP FOR VOLUNTARY RECALL

<u>Product Name/Product size</u>	<u>NDC Number</u>	<u>Product Code</u>	<u>Batch Number</u>	<u>Expiration Date</u>	<u>First Ship Date</u>	<u>Last Ship Date</u>
Fosaprepitant for Injection, 150 mg / vial in a 10 mL vial	63323-972-10	972010	6122760	08/2021	09/30/2019	12/30/2019
			6122761	08/2021	12/30/2019	04/06/2020
			6122762	09/2021	12/02/2019	06/16/2020
			6123883	03/2022	05/20/2020	06/22/2020

Vials (1 each) OR

Trays/Cartons Returning (Circle One)

Hospital (other) _____

Street Address _____

City, State, Zip code _____

Signature _____

PLEASE ENCLOSE THIS FORM WITH YOUR RETURN