



# URGENT DRUG RECALL

June 28, 2019

<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>
Fluorouracil Injection, USP, 5 g / 100 mL (50 mg / mL), 100 mL fill in a 100 mL vial	63323-117-61	101761	6120420	04-2020	12/07/2018	02/20/2019
	63323-117-69	NP101761	6120341	04-2020	12/06/2018	12/18/2018

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 Fluorouracil Injection, USP, 5 g / 100 mL (50 mg / mL), 100 mL fill in a 100 mL vial.

This recall is being performed to the user level. Fresenius Kabi USA, LLC has decided to take this action due to glass particulates found in 5 vials of the remaining inventory of batch 6120341 during an inspection for a quality investigation. Batch 6120420 is included in this recall as a precautionary measure because it was filled immediately post batch 6120341 as part of the same filling campaign.

The administration of glass particulate, if present in a parenteral drug, poses a moderate safety risk to patients. Reports in the literature suggest that sequelae of thromboembolism, such as pulmonary emboli, phlebitis, granulomas, or fibrosis may occur. No complaints related to glass particulate or adverse drug events have been received for either of these batches.

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.
3. **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

Fresenius Kabi USA, LLC  
2045 N. Cornell  
Melrose Park, IL 60160

Main: 708-343-6100  
Toll Free: 888-391-6300  
[www.fresenius-kabi.com/us](http://www.fresenius-kabi.com/us)

**URGENT PRODUCT RECALL RESPONSE FORM**

**URGENT: DRUG RECALL - Sterile Injectable**

June 28, 2019

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>
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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.

- 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>
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**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***

Fresenius Kabi USA, LLC  
2045 N. Cornell  
Melrose Park, IL 60160

Main: 708-343-6100  
Toll Free: 888-391-6300  
[www.fresenius-kabi.com/us](http://www.fresenius-kabi.com/us)