

URGENT DRUG RECALL

May 22, 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>
Ondansetron Injection, USP, 40 mg / 20 mL (2 mg / mL), 20 mL fill in a 20 mL amber vial	63323-374-20	370420	6018699	12-2021	03/13/2019	04/22/2019

Dear Customer/Health Professional:

This letter is to notify you that Fresenius Kabi USA, LLC ("Fresenius Kabi") is voluntarily recalling the above-mentioned batch of Ondansetron Injection, USP, 40 mg / 20 mL (2 mg / mL), 20 mL fill in a 20 mL amber vial (see Attachment 1 for vial label).

This recall is being performed to the user level. Fresenius Kabi USA, LLC has decided to take this action due to out-of-specification (OOS) results for Ondansetron Related Compound D (an impurity) at the 3-month stability test station. The investigation reveals that this issue is limited to the product batch indicated above.

The impurity was assessed by an independent toxicologist who confirmed low potential risk to patients due to the increased level of Ondansetron Related Compound D. No adverse event reports have been received for this batch number.

You are required to return all product from the above-mentioned batch 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 batch. Quarantine any affected stock. If you are a distributor, immediately notify your customers that have been shipped or may have been shipped this product of this recall and direct them to quarantine and discontinue distributing or dispensing the affected batch. 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 batch available, **immediately quarantine and discontinue distributing, or dispensing** any vials from the batch, 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
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.us

Attachment 1

Vial label for Ondansetron Injection, USP, 40 mg / 20 mL (2 mg / mL), 20 mL fill in a 20 mL amber vial, product code 370420

NDC 63323-374-20 370420

ONDANSETRON
INJECTION, USP

40 mg/20 mL ||

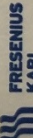
(2 mg/mL)

For IM or IV Use Rx only

20 mL Multiple Dose Vial

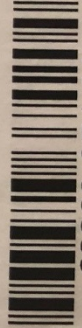
Sterile
Each mL contains ondansetron 2 mg, as the hydrochloride; sodium chloride, 8.3 mg; citric acid monohydrate, 0.5 mg and sodium citrate dihydrate, 0.25 mg as buffers; methylparaben 1.2 mg and propylparaben 0.15 mg as preservatives; and water for injection, q.s.

Usual Dosage: See insert.
Store at 2° to 25°C (36° to 77°F).
Protect from light.

 **Fresenius Kabi USA, LLC**
Lake Zurich, IL 60047

LOT/EXP 402171C

6018699
12/21

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URGENT PRODUCT RECALL RESPONSE FORM
URGENT: DRUG RECALL - Sterile Injectable
May 22, 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>
Ondansetron Injection, USP, 40 mg / 20 mL (2 mg / mL), 20 mL fill in a 20 mL amber vial	63323-374-20	370420	6018699	12-2021	03/13/2019	04/22/2019

1. Examine your inventory **immediately** to determine if you have any product from the above-mentioned batch.
2. If so, **immediately** discontinue distribution or dispensing of the affected batch 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 number 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.us