FRESENIUS KABI

URGENT DRUG RECALL

May 22, 2019

Product Name/Product size	NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
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 **DESTROY** 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 **DESTROY** the product. 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, dispensing, or using the batch, and **DESTROY** all vials using your current vendor / hauler of non-hazardous regulated medical waste. A credit memo will **NOT** be issued covering the quantity until a letter of destruction is received from you.

3. **PLEASE COMPLETE THE ENCLOSED "URGENT PRODUCT RECALL RESPONSE FORM" AND SEND IT BACK TO US 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

Number	Department	Reason to Call
(866) 716-2459	Quality Assurance Department	Information on how to return product
(800) 551-7176	Vigilance or Medical Affairs	For clinical/technical information/Adverse Events (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,

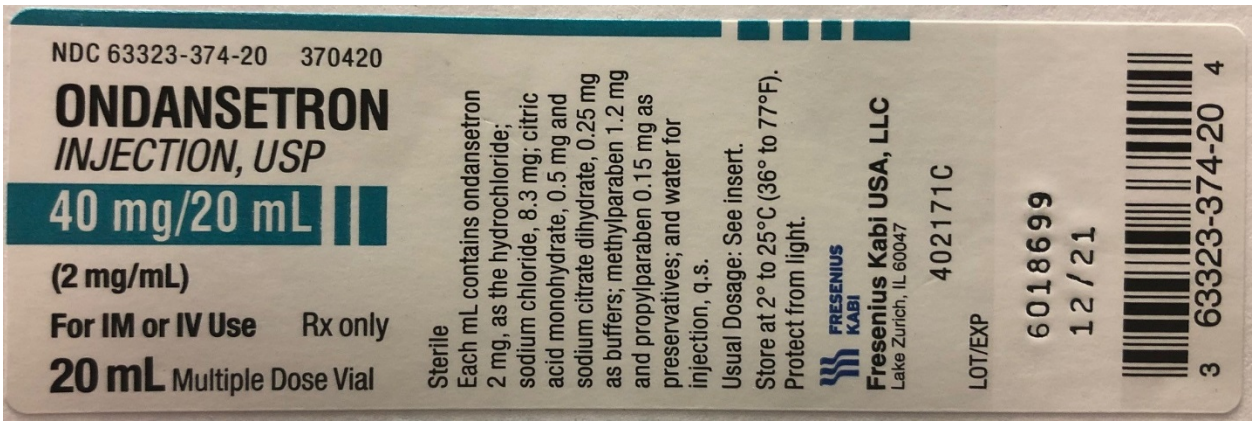
Melanie Power-Burns
Vice President Quality Assurance

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



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

Main: 708-343-6100
Toll Free: 888-391-6300
www.fresenius-kabi.us

FRESENIUS KABI

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

Product Name/Product size	NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
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 **DESTROY** all units using your current vendor / hauler of non-hazardous regulated medical waste. A credit memo will NOT be issued covering the quantity until a letter of destruction is received from you.
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 number on hand.

☐ We are **DESTROYING** _____ vials **OR** _____ trays/cartons

☐ I have identified and contacted direct account customers indicated below that have been shipped or may have been shipped this product. They have prepared to **DESTROY** the product.

FROM: Hospital (other):_____

Street Address:_____

City, State, Zip code: _____

Signature:_____

From:

FACILITY:
ADDRESS:
CITY, STATE, ZIP:

Signature _____ **Date** _____

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

Main: 708-343-6100
Toll Free: 888-391-6300
www.fresenius-kabi.us