

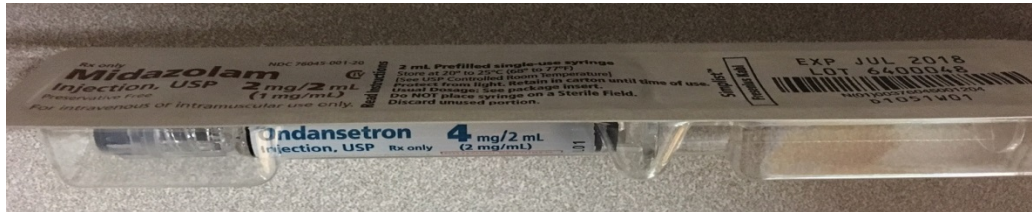
URGENT DRUG RECALL

October 30, 2017

<u>Product Name/Product size</u>	<u>NDC Number</u>	<u>Product Code</u>	<u>Lot Number</u>	<u>Expiration Date</u>	<u>First Ship Date</u>	<u>Last Ship Date</u>
Midazolam Injection, USP; 2 mg/2mL; 1 mL fill in a 2 mL single use glass syringe packaged in a blister package	76045-001-20	766120	6400048	07/18	05/12/2017	10/18/2017

Dear Customer/Health Professional:

This letter is to notify you that Fresenius Kabi USA, LLC ("Fresenius Kabi"), is voluntarily recalling the above-mentioned product lot as a precautionary measure. This recall is being performed to the user level. Fresenius Kabi has decided to take this action due to a report of two blister packages (secondary) labeled as Midazolam Injection, USP 2 mg/2mL, lot 6400048 containing syringes of Ondansetron Injection, USP 4 mg/2mL, lot 6400069.



A blister package labeled as Midazolam Injection, USP, but containing an Ondansetron Injection syringe may lead to an initial product selection error; however the syringe in the blister package is visible and clearly correctly labelled as containing Ondansetron Injection, USP. There have been no medication errors or adverse events reported for this lot of Midazolam Injection, USP; 2 mg/2mL.

You are required to **DESTROY** all product from the above-mentioned lot 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 from the affected lot. 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 discontinue distributing or dispensing the affected lot. Please have them prepare to **DESTROY** the product. Your customers may retrieve the recall letter and response form at <http://www.fresenius-kabi.us/products/pharmaceutical-products/product-updates.html>.
2. If you have the affected lot available, **immediately discontinue distributing, dispensing, or using** the lot, 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 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 US Food and Drug Administration (FDA).

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

Sincerely,



Melanie Power-Burns
Vice President Quality Assurance and Compliance

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

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

URGENT PRODUCT RECALL RESPONSE FORM

URGENT: DRUG RECALL - Sterile Injectable

October 30, 2017

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>Lot Number</u>	<u>Expiration Date</u>	<u>First Ship Date</u>	<u>Last Ship Date</u>
Midazolam Injection, USP; 2 mg/2mL; 1 mL fill in a 2 mL single use glass syringe packaged in a blister package	76045-001-20	766120	6400048	07/18	05/12/2017	10/18/2017

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