URGENT DRUG RECALL

Ondansetron, 4 mg, 2 ml, Vial

Monday, November 20, 2023

Dear Valued Life-Assist Customer,

According to our records you may have purchased a product that is affected by the attached manufacturer recall notice. Please examine your inventory to determine if you have the following product in your possession.

Ondansetron, 4 mg, 2 ml, Vial

Life-Assist Product Code	Manufacturer Product Code	NDC	Lot # / SN
DR0012-25	AIN00237	36000-0012-25	A0E0865A, A0E0959A, A0E0961A, A0E1015A, A0E0959A, A0E0961A, A0E1015A, A0E1020A, A0F0016A, A0F0260A, A0F0261A, A0F0262A, A0F0414A, A0F0415A, A0F0416A, A0F0417A, A0F0418A, A0F0503A, A0F0533A, A0F0534A, A0F0535A, A0F0536A, A0F0537A, A0F0540A, A0F0541A, A0F0573A, A0F0574A, A0F0575A, A0F0592A, A0F0596A, A0F0599A, A0F0676A

Reason:
Baxter is issuing an Urgent Drug Recall for certain lots of Ondansetron Injection because the pH level parameter of these impacted lots may be out of specification.
Please read the enclosed notice from the manufacturer for more information.

Action Required:

1. Read the attached **URGENT DRUG RECALL** notification from the manufacturer.
2. Immediately forward this notification to any pertinent personnel, department, and/or location within your organization.
3. Check your inventory for the specific product identified in the table above and quarantine any affected product.
4. Contact Life-Assist Customer Care, CustomerCare@life-assist.com or 800-824-6016, to obtain a return authorization and to place and order for an available alternative.

Contact Life-Assist Customer Care with any questions or concerns.

We apologize for any inconvenience.

Baxter

Urgent Drug Recall

November 14, 2023

Dear Healthcare Provider:

Problem Description

Ondansetron Injection is used for the prevention of nausea and vomiting associated with initial and repeat courses of cancer chemotherapy, as well as postoperative nausea and vomiting. Baxter is issuing an Urgent Drug Recall for certain lots of Ondansetron Injection because the pH level parameter of these impacted lots may be out of specification.

See the table below for details on the product affected by this issue. Affected product were distributed between 3/25/2022 and 9/21/2023 in the United States.

Affected Product

Product Code	Product Description	Lot Numbers	Expiration Date	NDC #
AIN00237	Ondansetron INJ USP 2 mg/ml	See Attachment A	See Attachment A	36000-012-25

Hazard Involved

A minimally higher than specified pH level is not expected to pose a safety concern. There have been no reports of adverse events related to this issue.

Actions to be taken by Customers

1. Immediately locate, isolate, and cease all use of the affected product. The product code and lot number can be found on the product label and product carton.

2. Contact Baxter Healthcare Center for Service to arrange for return and credit. Baxter Healthcare Center for Service can be reached at 888-229-0001 between the hours of 7:00 am and 6:00 pm Central Time, Monday through Friday. Please have your Baxter 8-digit ship-to account number, product code, lot number, and quantity of product to be returned ready when calling.

3. **If you received this communication directly from Baxter, please acknowledge receipt of this notification by responding on our customer portal at https://BaxterFieldActionCustomerPortal.onprocess.com, even if you do not have any remaining inventory.** Log in to the portal using the account number listed in the enclosed reply form instruction sheet. Acknowledging receipt of this notification will prevent you from receiving repeat notices. If you do not complete the acknowledgement, you will receive a phone call from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification.

4. If you purchased this product from a distributor or wholesaler, please note that responding on the Baxter customer portal is not applicable. If a response is requested by your distributor or wholesaler, please respond to the supplier according to their instructions.

5. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.

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6. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please conduct a consumer-level recall of the affected product that you distributed to customers and **check the associated box on the customer portal.**

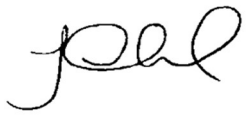
Further information and support For general questions regarding this communication, please contact Baxter Healthcare Center for Service at 888-229-0001 between the hours of 7:00 am and 6:00 pm Central Time, Monday through Friday.

The United States Food and Drug Administration (FDA) has been notified of this action. Any product quality complaints or adverse events experienced with the use of these products may be reported using one of the following options:

- Emailing Baxter at corporate_product_complaints_round_lake@baxter.com.
- Reporting to the FDA MedWatch Serious Injury Reporting Program:
  - **Online:** By completing and submitting the report online at: https://www.accessdata.fda.gov/scripts/medwatch/
  - **Regular mail or fax:** Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178

We apologize for any inconvenience this may cause you and your staff.

Sincerely,



Jeffrey Dihel
Vice President, Quality
Baxter Healthcare Corporation

Enclosures: Reply Form Instruction Sheet
Attachment A: Affected Lot numbers

Baxter

ATTACHMENT A – AFFECTED LOT NUMBERS

Product Code	Product Description	Lot Numbers	Expiration Date	NDC #
AIN00237	Ondansetron INJ USP 2 mg/ml	A0E0865A	31-Oct-2023	36000-012-25
		A0E0959A	30-Nov-2023	
		A0E0961A	30-Nov-2023	
		A0E1015A	30-Nov-2023	
		A0E1020A	30-Nov-2023	
		A0F0016A	31-Dec-2023	
		A0F0260A	29-Feb-2024	
		A0F0261A	29-Feb-2024	
		A0F0262A	29-Feb-2024	
		A0F0414A	30-Apr-2024	
		A0F0415A	30-Apr-2024	
		A0F0416A	30-Apr-2024	
		A0F0417A	30-Apr-2024	
		A0F0418A	30-Apr-2024	
		A0F0503A	31-May-2024	
		A0F0533A	30-Jun-2024	
		A0F0534A	30-Jun-2024	
		A0F0535A	30-Jun-2024	
		A0F0536A	30-Jun-2024	
		A0F0537A	30-Jun-2024	
		A0F0540A	30-Jun-2024	
		A0F0541A	30-Jun-2024	
		A0F0573A	31-Jul-2024	
		A0F0574A	31-Jul-2024	
		A0F0575A	31-Jul-2024	
		A0F0592A	31-Jul-2024	
		A0F0596A	31-Aug-2024	
		A0F0599A	31-Aug-2024	
		A0F0676A	31-Oct-2024	

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