

## RECALL LETTER

### URGENT: OMEPRAZOLE AND SODIUM BICARBONATE POWDER FOR ORAL SUSPENSION 40 MG/1,680 mg (Zegerid) RECALL

Jan 31, 2024

Nageswara Rao Guthula  
Sr. Director, External Manufacturing Quality-US  
Bausch Health Companies, Inc.  
400 Somerset Corporate Boulevard  
Bridgewater, NJ 08807

Dear Valued Customer,

Salix Pharmaceuticals, Inc., a subsidiary of Bausch Health Companies Inc., is conducting a voluntary recall at the wholesale/distribution level. **Please immediately stop all sales or distribution of Lot 0013R and quarantine the product (See enclosed product label).**

Product Name	NDC #	Lot#	Exp. Date	Distribution Dates
Omeprazole and Sodium Bicarbonate Powder for Oral Suspension 40 mg/1,680 mg	68682-991-30	0013R	Jan 2026	31 Aug 2023 to 21 Dec 2023

This voluntary recall was initiated out of an abundance of caution due to an out-of-specification result observed during stability. The possibility for any immediate and/or adverse health consequences resulting from this issue is remote. Bausch Health Companies Inc. is conducting a voluntary recall at a wholesale level.

This recall is being made with the knowledge of the U.S. Food and Drug Administration.

Please complete and return the enclosed Recall Return Response form as soon as possible. Return the completed Recall Return Response Form to Inmar, the firm managing this voluntary recall on behalf of Bausch Health Companies Inc., via email ([rxrecalls@inmar.com](mailto:rxrecalls@inmar.com)), fax (1-817- 868-5362) or mail (Inmar, 1 West 4th St Suite 500, Winston Salem, NC 27101) within 5 days. It is important to return the Recall Return Response Form even if you do not have any Omeprazole and Sodium Bicarbonate Powder for Oral Suspension 40 mg/1,680 mg, Lot 0013R, in your inventory.

Upon receipt of the Recall Return Response form by Inmar, if your facility has noted having an inventory of Lot 0013R, a return kit with a prepaid shipping label will be sent to you to return the product. Appropriate credit for product returns, handling, and shipping expenses will be issued upon receipt of the impacted product via the return kit. Recalled product returned without a return kit may delay the issuance of your credit.

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### URGENT: OMEPRAZOLE AND SODIUM BICARBONATE POWDER FOR ORAL SUSPENSION 40 MG/1,680 mg (Zegerid) RECALL

Your assistance is appreciated and necessary to prevent further distribution of this lot. We apologize for any inconvenience this may cause. If you have any questions, please contact Bausch Health Companies Inc., Customer Care via phone at 800-321-4576 (opt 2 / inquiries) or by email at [bauschhealthcustomercare@bauschhealth.com](mailto:bauschhealthcustomercare@bauschhealth.com).

Sincerely,



31 JAN 2024

Guthula Nageswara Rao

Sr. Director, External Manufacturing Quality-US

**URGENT DRUG PRODUCT RECALL  
RECALL RETURN RESPONSE FORM**  
**Omeprazole and Sodium Bicarbonate Powder for Oral Suspension**  
**40 mg/1,680 mg (Zegerid), Lot 0013R**  
**Wholesale Level – 01/31/2024**

RCL032-2024 / N131977

**Please fill out this form completely.** By doing so, this will acknowledge that you have read and understand the recall instructions and have taken the appropriate action.

Customer Name: \_\_\_\_\_ DEA#: \_\_\_\_\_  
*DEA # is required, if it is not provided, the processing of your form will be delayed.*

Address: \_\_\_\_\_  
City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Contact Name (Please Print): \_\_\_\_\_

Telephone#: \_\_\_\_\_ Email: \_\_\_\_\_

Contact Signature: \_\_\_\_\_ Date: \_\_\_\_\_

DEBIT MEMO# (If unsure, leave blank): \_\_\_\_\_

**Wholesaler Information if not directly purchased from Bausch Health Companies, Inc.:**

Wholesaler Name: \_\_\_\_\_ DEA#: \_\_\_\_\_  
City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

**Please review and acknowledge (X) on one of the statements below that applies to your facility:**

- I have checked my stock and do NOT have any inventory.
- I have checked my stock and have quarantined inventory. Please fill out the table below with the quantity of recalled units to be returned to Inmar.

Item Description	NDC #	Lot#	Exp Date	Full Cartons	Partial Cartons	Sachet Count in Partial Cartons
Omeprazole and Sodium Bicarbonate Powder for Oral Suspension 40 mg/1,680 mg (Zegerid)	68682-991-30	0013R	Jan 2026			

Upon receipt of this Response Form, Inmar, will issue return authorization label(s). Please indicate the # of needed box labels \_\_\_\_\_.

If you have any questions regarding this form or product return please contact Inmar at 877-814-3186  
Office hours 9am to 5pm EST Mon thru Fri.

**Please complete, sign, and return this form to:**

**Fax:** 1-817-868-5362

**Email:** [rxrecalls@inmar.com](mailto:rxrecalls@inmar.com)

**Phone:** 1-877 814 3186

**Mailing Address:** 1 W 4th St Suite 500 Attn: Rx Recall Dept, Winston Salem, NC 27101

RCL032-2024 / N131977