400 Somerset Corporate Boulevard Bridgewater,
New Jersey 08807
908 927 1400
bauschhealth.com

URGENT RECALL

Omeprazole and Sodium Bicarbonate Powder for Oral Suspension 40 mg/1,680 mg

05 March 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 retail level (Class II). Please immediately stop all sales or distribution of Lot 0013R and quarantine the product (See enclosed product label).

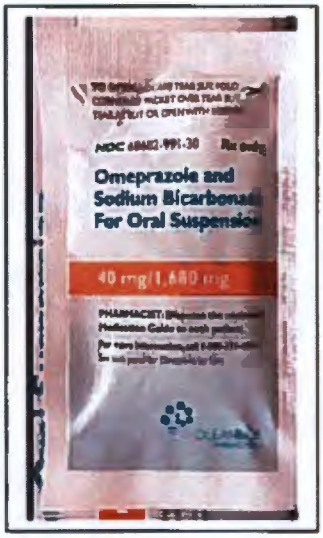
Product Name	NDC #	Lot#	Exp. Date	Distribution Dates
Omeprazole and Sodium Bicarbonate Powder for Oral Suspension 40 mg/1,680 mg	68682-991-30	0013R	Jan 2026	31 Aug 2023 to 21 Dec 2023

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.

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

EXAMPLE OF PRODUCT IMAGE:

LOT 0013R Sachet



LOT 0013R Carton

BAUSCH Health

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We ask that you please have your customers quarantine all units in your possession and take the following steps to return the Omeprazole and Sodium Bicarbonate Powder for Oral Suspension 40 mg/1,680 mg, Lot 0013R product included in this voluntary recall to Bausch Health US, LLC.

We ask that you please take the following steps to return the product:

1. Please check you inventory for the matching lot number listed and segregate it for return shipment. The product can be most easily identified by checking the lot number on the cartons and the sachets to see if it matches Lot 0013R. The above images show how to identify the lot on the Sachet and Carton.

2. Please complete the enclosed Recall Acknowledgement Form and return it within 5 days. It is important to return this card even if there is no remaining inventory of the lot mentioned above. Please fax this form to: 1-817-868-5362 or email it to: rxrecalls@inmar.com.

3. Segregate any of the impacted product identified in your inventory and ensure it is not further distributed.

4. Please contact your retailers that were shipped the recalled product with a copy of this recall letter and ask that they complete the recall acknowledgement form and arrange for the return of the product identified from their current inventory to Inmar, Inc. If you would like Inmar to perform the recall notification to your retailers that were shipped the product being recalled, please email an excel spreadsheet with the retailer's contact information to rxrecalls@inmar.com within 5 business days.

If you have questions about this recall or would like additional information, please contact Inmar, Inc., the firm managing this voluntary product recall on behalf of Salix Pharmaceuticals at (877) 814-3186. We greatly appreciate your prompt assistance and apologize for any inconvenience this may cause.

Note: This Recall Letter is being amended based upon U.S. FDA's Recall Classification.

Sincerely,

03/05/2024

Guthula Nageswara Rao
Sr. Director, External Manufacturing Quality-US

BAUSCH Health

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URGENT DRUG PRODUCT RECALL

RECALL RETURN RESPONSE FORM

Omeprazole and Sodium Bicarbonate Powder for Oral Suspension 40 mg/1,680 mg (Zegerid), Lot 0013R

Retail Level – 03/01/2024

RCL003-2024 N021636

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):

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

Retailer 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 **Phone:** 1-877 814 3186

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