

URGENT PRODUCT RECALL COMMUNICATION / CUSTOMER NOTIFICATION
Buspirone Hydrochloride Tablets, USP

April 10, 2026

Dear Valued Customer:

This letter is to inform you that Unichem Pharmaceuticals (USA), Inc. is voluntarily recalling the following products listed immediately below:

| Product Description | Lot Number | NDC Number | Distribution Date |
|---|--|-------------------|-----------------------------|
| Buspirone Hydrochloride Tablets, USP Strength: 5 mg Pack size: 500 count bottles | ZBUL25001 Exp 2027/12 | 29300-244-05 | 08/08/2025 to 08/18/2025 |

Unichem Pharmaceuticals (USA), Inc. is initiating a voluntary recall from the US market (**to the Retail level**) for bottles of product labeled as “Buspirone Hydrochloride Tabs, 5mg, 500 Count Bottle, Lot **ZBUL25001**” due to an out-of-specification (OOS) assay result identified at the 12-month long-term stability time point.

This recall is being made with the full knowledge of the United States Food and Drug Administration and should be carried out to the **Retail level**. Unichem has not received any reports of any adverse events related to this recall to date.

Buspirone Hydrochloride tablets are indicated for the management of anxiety disorders or the short-term relief of the symptoms of anxiety.

Unichem Pharmaceuticals (USA), Inc., began shipping this batch to customers nationwide in August 2025.

Please complete and return the enclosed recall response form as soon as possible. Subsequently, please examine your inventory and quarantine the product specific to the subject recall. Additionally, if you have further distributed this product, please identify and notify your retail customers at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

The product should be identified by verifying both the product name and the specific lot number on the product label.

To implement this recall, please take the following actions:

1. Immediately examine your inventory and quarantine product subject to this recall.
2. Immediately discontinue distribution of the identified lot numbers. A credit memo will be issued covering the quantity of your product returned.

3. Return product to:

Inmar
Ref No. RCL079-26
3845 Grand Lakes Way, STE 125,
Grand Prairie, Texas 75050

NOTE: A recall packet, inclusive of a call tag, a pre-printed, pre-paid return label will be provided to you for product return; return shipment is free of charge. For the call tag, contact 1-877-411-9329.


Wholesalers/Retailers: No call necessary, just send complete response form via email: rxrecalls@inmar.com or fax to 1-817-868-5362.

4. If you have further distributed this product and Lot Number to other **retailers**, please identify and notify them at once of this product recall. Your notification should include a copy of this recall notification letter and response form.
5. Please complete and return the enclosed "Customer Recall Return Response Form" as soon as possible and fax the form to us at **1-817-868-5362** or email to **rxrecalls@inmar.com**.

Once the business response form is received by Inmar, a Return Goods Authorization form will be sent to you. Please return your product along with the Return Authorization using the postage paid shipping label included in your recall return packet. Appropriate reimbursement for product returns will be issued on receipt of the recalled product.

We apologize for any inconvenience this may cause you. If you should have any questions, please do not hesitate to contact Inmar **1-877-411-9329**; Monday – Friday (9 am – 5 pm; CST).

Sincerely,

 04/10/2026 (Kanwaljit Uppal, Signed on Behalf)

Jennifer Perry
AVP & Regional Health of Quality
Unichem Pharmaceuticals (USA), Inc.
1 Tower Center Boulevard,
East Brunswick, New Jersey 08816 (USA)

RECALL STOCK RESPONSE FORM – RCL079-26,

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 for all Controlled Substances, if not provided, processing of your form will be delayed.***

Address _____

City _____ **State** _____ **Zip** _____

Contact Name (please print) _____ **Telephone #** _____

Contact Signature _____ **Date** _____

Please Complete (check ALL applicable):

- I have read and understand the recall instructions provided in the recall letter and that this recall is now being carried out to the retail level.
- I have checked my inventory and have quarantined the subject product, we possess _____ units of the same.
- I have or will contact those we further distributed the subject product regarding this recall out to the retail level.
- Indicate disposition of this recalled product:

| Item Description | Lot Number | NDC Number | QTY Returning |
|------------------|------------|------------|---------------|
| | | | |

Other: _____

Check the appropriate box(s) to describe your business:

- Wholesaler/Distributor Hospital/Medical Facility Pharmacy (retail)

Other: _____

Name of Wholesaler & Address:

If you have any questions regarding this form or product return, please contact us at:

1+ (877) 411-9329. Office hours Monday – Friday (9 am – 5 pm; CST).

PLEASE SEND THIS COMPLETED RECALL RESPONSE FORM TO:

FAX: 1+ (817) 868-5362 EMAIL TO: rxrecalls@inmar.com

MAIL: Inmar, 3845 Grand Lakes Way, STE 125, Grand Prairie, Texas 75050

The product label is shown below:

NDC 29300-244-05

Each tablet contains:
Buspirone Hydrochloride, USP... 5 mg

Usual Dosage:
See Accompanying Package Insert.

Store at 20° to 25°C (68° to 77°F).
[see USP Controlled Room Temperature].

Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

KEEP THIS AND ALL DRUGS OUT OF REACH OF CHILDREN.



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03-R-12/2019

busPIRone
Hydrochloride
Tablets, USP

5 mg

R_x Only 500 Tablets



UNICHEM
PHARMACEUTICALS (USA), INC.

M.L. 14 of 74
Manufactured by: **UNICHEM LABORATORIES LTD.**
Ind. Area, Meerut Road, Ghaziabad -201 003, India,
Manufactured for: **UNICHEM PHARMACEUTICALS (USA), INC.**
East Brunswick, NJ 08816.