

CUSTOMER NOTIFICATION/ RECALL COMMUNICATION
URGENT: Topiramate Tablets, USP, 50 mg, 500's pack
RETAIL LEVEL RECALL

October 25, 2021

Dear Valued Customer:

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

Product	Lot Number	NDC Number	Distribution Date
Topiramate Tablets, USP, 50 mg, 500's pack	ZTPM20044 Exp.: 09/30/22	29300-116-05	November 2020 through September 2021

This recall has been initiated due to a greyish to black discoloration on the surface of the tablets.

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

To implement this recall, please take the following actions:

1. Immediately examine your inventory and quarantine product subject to recall.
2. Immediately discontinue use and distribution of the identified lot numbers. A credit memo will be issued covering the quantity of your product returned.
3. Return product to: **Inmar**
3845 Grand Lakes Way, STE 125, Grand Praire, Texas 75050

NOTE: 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 1-855-825-1449.

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

4. If you have further distributed this product 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.

We apologize for any inconvenience this may cause you. If you have any questions, please do not hesitate to contact us at **1-855-825-1449**; Monday – Friday (9 am – 5 pm; CST).

Sincerely,



Kartik M. Keertikar
Senior Manager, Regulatory Affairs

RECALL STOCK RESPONSE FORM

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 #** _____

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 wholesale/retail level.
- I have checked my inventory and have quarantined the product consisting of _____ units.
- I have or will contact those further distributed to, to recall out to the wholesale/retail user level.
- Indicate disposition of this recalled product:

Item Description	Lot Number	NDC Number	QTY Returning
Topiramate Tablets, USP, 50 mg, 500's pack	ZTPM20044; Exp.: 09/30/22	29300-116-05	

Other: _____

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

- Wholesaler/distributor Hospital/medical facility
- Pharmacy-retail Other: _____

If you have any questions regarding this form or product return, please contact us at:
1-855-825-1449. 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