

RECEIVED

JUL 03 2020



URGENT DRUG RECALL

June 25, 2020

Product Name	Description	NDC	Batch/Lot	Expiry Date
Carbamazepine Tablets USP	200 mg, 500's Count	13668-268-05	4FF4F001	01/2023

Dear Customer,

Torrent Pharmaceuticals Limited is extending the voluntary recall of Carbamazepine Tablets USP 200 mg from Wholesale level to Retail Level. Our records indicate that you have purchased product from the subject batch/lot. No other strengths or batches of this product are subject to this recall. This recall is being conducted with the knowledge of the Food and Drug Administration.

This recall is based upon a out of specification dissolution result obtained during routine stability testing for this batch. Considering all available information, it is determined that the failure result would not have a clinically significant impact on safety and efficacy. There were no adverse event or product complaint cases received for this batch. Hence, based on available data, there is a minimal chance of health hazard.

Torrent Pharmaceuticals Limited requests that you immediately take the following actions:

1. Immediately examine your inventory, quarantine product subject to the recall and Stop distribution of the lot identified above.
2. Please complete the enclosed Business Response Form indicating either:
 - a. You have examined your inventory and have none of the recalled product in Stock or,
 - b. Upon examining your inventory you have found the effected recall product which will be quarantined. In the event you have Recall product, please return to Qualanex, LLC., using the enclosed Postage Paid Product Return label and mail to the following:

Qualanex, LLC.
1410 Harris Road
Libertyville, IL 60048

3. Please return the enclosed Business Response Form via fax to 1-847-737-3719 or email to Recall@qualanex.com.

This action applies only to the products and lots addressed in this notification. Only product from this batch/lot will be accepted under the terms of this recall.

- If you have any general questions regarding the return of this product please contact Qualanex at 1-800-505-9291.
- If you have any medical questions regarding this recall, please contact Torrent Pharma Inc. at 1-800-912-9561 (8:00 am – 5:00 pm Eastern Time).

We regret any inconvenience and appreciate your immediate cooperation.

A handwritten signature in blue ink that reads "Kristy Zielny".

Kristy Zielny
Sr. Director, Quality

13668-00275-01003208
DROGUERIA BETANCES, INC
AVE. LUIS MUNOZ MARIN
ESQUINA TROCHE ANGORA EL TROCHE
CAGUAS, PR 725

URGENT DRUG RECALL BUSINESS RESPONSE FORM

Product Name	Description	NDC	Batch/Lot	Expiry Date
Carbamazepine Tablets USP	200 mg, 500's Count	13668-268-05	4FF4F001	01/2023

Please fill out and either fax to (847) 737-3719 or email to Recall@qualanex.com.

Quantity Being Returned Full/Sealed Bottles Partial Bottles Tablet Count of Partial Bottles

We have examined our inventories and have none of the above recalled product in stock: (initials) _____

Completed by: (Please Print)

Name/Title: _____

Company Name: _____

Address: _____

City: _____ State: _____ Zip: _____

DEA Number: _____

Date: _____

Phone: _____ Fax #: _____

Email: _____

Wholesaler Name: _____

Wholesaler Acct. #: _____

DEA Number: _____

Signature: _____