



URGENT DRUG RECALL
December 01, 2021

NDC	Product Name, Strength and Package Count	Batch Number	Expiration Date
13668-159-30	Telmisartan and Hydrochlorothiazide Tablets, USP 40/ 12.5 mg, 30 Count	BZ74G001	12/2021

Dear Customer,

Torrent Pharmaceuticals Limited is initiating a voluntary recall of Telmisartan and Hydrochlorothiazide Tablets USP, 40/ 12.5 mg to the 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 high out of specification Assay result of Hydrochlorothiazide detected during routine stability testing for this batch. Considering all available information, it is determined that the slight increase in Assay 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 product subject to this recall, 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 product and lot 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.

Kristy Zielny
Sr. Director, Quality

URGENT DRUG RECALL BUSINESS RESPONSE FORM

(Torrent Recall #323)

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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: _____

Wholesaler Acct. #: _____

DEA Number: _____

Signature: _____