Clifton Health Department
Food Recall Notification

Public Health
Prevent. Promote. Protect.

Food/Drug/Pet Recall: Torrent Pharmaceuticals

Torrent Pharmaceuticals Limited is expanding its recall for Losartan Potassium Tablets USP and Losartan Potassium/hydrochlorothiazide tablets, USP, to the consumer level due to the detection of trace amounts of an unexpected impurity found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited.

The Recall is expanded to include an additional 36 lots of Losartan potassium Tablets USP and 68 lots of Losartan Potassium/Hydrochlorothiazide Tablets, USP

The impurity detected in the API is N-Methylnitrosobutyric acid (NMBA). Torrent is only recalling lots of losartan-containing products that contain N-Methylnitrosobutyric acid (NMBA) above the acceptable daily intake levels released by the FDA.

To date, Torrent Pharmaceuticals Limited has not received any reports of adverse events related to this recall.

Losartan is used to treat hypertension, hypertensive patients with Left Ventricular Hypertrophy and for the treatment of nephropathy in Type 2 diabetic patients. Losartan potassium and hydrochlorothiazide tablets, USP is used to treat hypertension and hypertensive patients with Left Ventricular Hypertrophy.

Patients who are taking Losartan Potassium Tablets, USP and Losartan Potassium/Hydrochlorothiazide Tablets, USP should continue taking their medication, as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication.

The product/lots included in the expanded recall are listed below in the second table. The product can be identified by checking the product name, manufacturer details and batch or lot number on the bottle containing these products.

The full list of recalled lots may be accessed at this weblink:
https://www.fda.gov/Safety/Recalls/ucm636296.htm?utm_campaign=Updated%3A%20Torrent%20Pharmaceuticals%20Limited%20Expands%20Voluntary%20Recall%20of%20Losartan%20Potassium%20Tablets&utm_medium=email&utm_source=Eloqua

Losartan potassium tablets, USP and Losartan potassium/ hydrochlorothiazide tablets, USP were distributed nationwide to Torrent's wholesale distributor, repackager and retail customers. Torrent Pharmaceuticals Limited is notifying its distributors and customers by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. Torrent is arranging for return of all recalled products to Qualanex.

Instructions for returning recalled products are given in the recall letter.

Consumers with medical questions regarding this recall or to report an adverse event can contact Torrent Pharmaceuticals Limited at:

. 1-800-912-9561 (live calls received 8:00 am - 5:00 pm Eastern Time, voicemail available 24 hours/day, 7 days/week).
. Medinfo.Torrent@apcerls.com

Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Any general questions regarding the return of this product should be directed to Qualanex at 1-888-280-2040 (live calls received 8 am - 9:00 pm Eastern Time).
Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Complete and submit the report Online: www.fda.gov/medwatch/report.htm
Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm
Call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178