COMPANY ANNOUNCEMENT

Updated: Torrent Pharmaceuticals Limited Expands Voluntary Nationwide Recall of Losartan Potassium Tablets, USP and Losartan Potassium / Hydrochlorothiazide Tablets, USP

Summary

Company Announcement Date:

September 19, 2019

FDA Publish Date:

September 19, 2019

Product Type:

Drugs

Reason for Announcement:

Due to the Detection of N-Methylnitrosobutyric acid (NMBA)

Company Name:

Torrent Pharmaceuticals Limited

Brand Name:

Torrent Pharma

Product Description:

Losartan Potassium Tablets, USP and Losartan Potassium/Hydrochlorothiazide Tablets, USP

Company Announcement

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 while testing the below finished product batches manufactured utilizing active pharmaceutical ingredient (API) manufactured by Hetero

Labs Limited using the old Route of Synthesis. The recall is expanded to include an additional 3 lots of Losartan Potassium Tablets USP and 2 lots of Losartan Potassium/Hydrochlorothiazide Tablets, USP.

The impurity detected 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.

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. The product can be identified by checking the product name, manufacturer details and batch or lot number on the bottle containing these products.

Losartan Potassium Tablet and Losartan Potassium / Hydrochlorothiazide Tablet Lots

NDC	Product Name, Strength and Package Count	Batch Number	Expiration Date
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E009	12/31/2020
13668-115-90	Losartan Potassium Tablets, USP 100mg, 90 count	4DU3E009	12/31/2020
13668-115-10	Losartan Potassium Tablets, USP 100mg, 1000 count	4DU3D018	02/28/2021
13668-116-90	Losartan Potassium / Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	BEF7D051	11/30/2020
13668-118-90	Losartan Potassium / Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count.	4P04D007	07/31/2020

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 (mailto: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 (http://www.fda.gov/medwatch/report.htm)
Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm (http://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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Link to Original Recall (/safety/recalls-market-withdrawals-safety-alerts/torrent-pharmaceuticals-limited-expands-voluntary-nationwide-recall-losartan-potassium-tablets-usp)
Link to 1st Expansion Recall (/safety/recalls-market-withdrawals-safety-alerts/torrent-pharmaceuticals-limited-expands-voluntary-nationwide-recall-losartan-potassium-tablets-usp)
Link to 2nd Expansion Recall (/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall-losartan-potassium)
Link to 3rd Expansion Recall (/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall-losartan-potassium-0)
Link to 4th Expansion Recall (/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-expands-voluntary-nationwide-recall-losartan-potassium)

Company Contact Information

Consumers:

Torrent Medical Information

1-800-912-9561

Medinfo.Torrent@apcerls.com (mailto:Medinfo.Torrent@apcerls.com)

Product Photos

1000 Tablets NDC 13668-409-10

Losartan Potassium Tablets USP

50 mg

PHARMACIST: PLEASE DISPENSE WITH PATIENT INFORMATION LEAFLET PROVIDED SEPARATELY

Rx only

torrent PHARMA

Manufactured by:
TORRENT PHARMACEUTICALS LTD.
Bharuch-392130, INDIA.

Manufactured for:
TORRENT PHARMA INC.
Basking Ridge, NJ 07920.

Each tablet contains 50 mg of losartan potassium, USP.
Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) [see USP Controlled Room Temperature].
Protect from light.
Dispense in a tight, light-resistant container with a child-resistant closure.
Usual Dosage:
See accompanying prescribing information.
Mfg. Lic. No.: G/25/2010

8056010

N 3 13668-409-10 9

90 Tablets NDC 13668-115-90

Losartan Potassium Tablets USP

100 mg

PHARMACIST: PLEASE DISPENSE WITH ATTACHED PATIENT INFORMATION LEAFLET

Rx only

torrent PHARMA

Manufactured by:
TORRENT PHARMACEUTICALS LTD.
Bharuch-392130, INDIA.

Manufactured for:
TORRENT PHARMA INC.
Basking Ridge, NJ 07920.

Each tablet contains 100 mg of losartan potassium, USP.
Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) [see USP Controlled Room Temperature].
Protect from light.
Dispense in a tight, light-resistant container with a child-resistant closure.
Usual Dosage:
See accompanying prescribing information.
Mfg. Lic. No.: G/25/2010

8070937

N 3 13668-115-90 1

1000 Tablets NDC 13668-115-10

Losartan Potassium Tablets USP

100 mg

PHARMACIST: PLEASE DISPENSE WITH PATIENT INFORMATION LEAFLET PROVIDED SEPARATELY

Rx only

torrent PHARMA

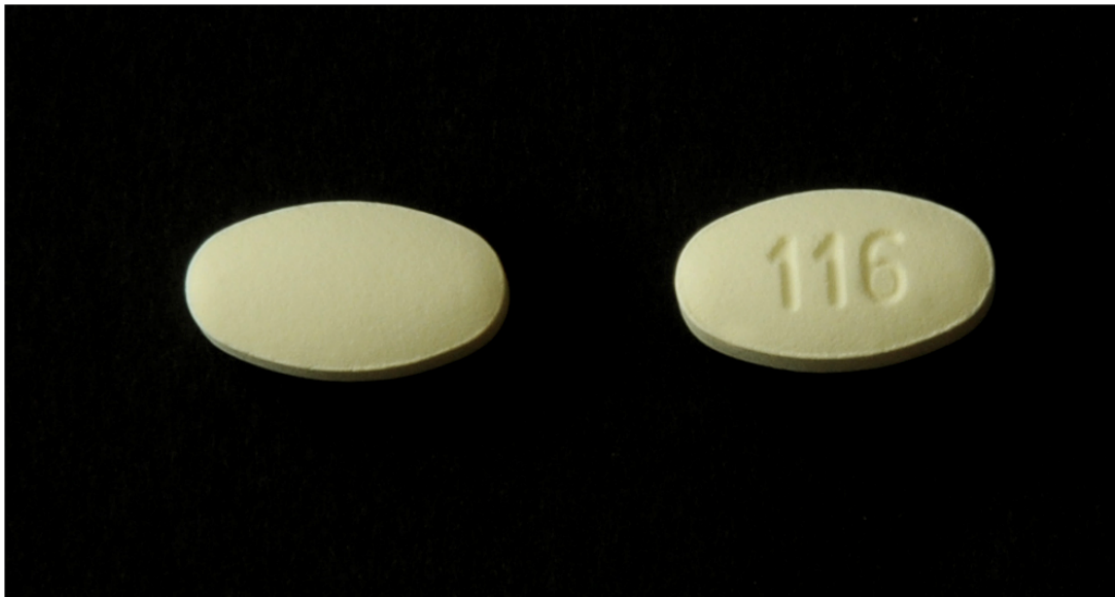
Manufactured by:
TORRENT PHARMACEUTICALS LTD.
Bharuch-392130, INDIA.

Manufactured for:
TORRENT PHARMA INC.
Basking Ridge, NJ 07920.

Each tablet contains 100 mg of losartan potassium, USP.
Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) [see USP Controlled Room Temperature].
Protect from light.
Dispense in a tight, light-resistant container with a child-resistant closure.
Usual Dosage:
See accompanying prescribing information.
Mfg. Lic. No.: G/25/2010

8056013

N 3 13668-115-10 9



NDC 13668-116-90

LOSARTAN POTASSIUM and HYDROCHLOROTHIAZIDE Tablets, USP

50 mg/12.5 mg

90 tablets

Rx only

PHARMACIST : PLEASE DISPENSE WITH ATTACHED PATIENT INFORMATION SHEET.

Each tablet contains 50 mg losartan potassium, USP and 12.5 mg hydrochlorothiazide, USP.
Store at 20° to 25°C (68° to 77°F) (See USP controlled room temperature).
Protect from light.
Dispense in a tight, light-resistant container with a child-resistant closure.
Usual Dosage: See accompanying prescribing information.

torrent PHARMA Mfg. Lic. No. : G/925

Manufactured by :
TORRENT PHARMACEUTICALS LTD.
Indrad-382 721, Dist. Mehsana, INDIA.
For : TORRENT PHARMA INC.
150 Allen Road, Suite 102
Basking Ridge, NJ 07920.

8045078

N 3 13668-116-90 8

More Recalls, Market Withdrawals, & Safety Alerts (/safety/recalls)