Company Announcement

UPDATED: Torrent Pharmaceuticals Limited Issues Voluntary Nationwide Recall of Losartan Potassium Tablets, USP and Losartan Potassium and Hydrochlorothiazide Tablets, USP

For Immediate Release

January 22, 2019

Contact

Consumers

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1-800-912-9561

Announcement

View Product Photos

Torrent Pharmaceuticals Limited is expanding its voluntary recall from 10 lots of Losartan potassium tablets USP to include 6 lots of Losartan potassium and 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 impurity detected in the API is N-nitrosodiethylamine (NDEA), which is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen as per international Agency for Research on Cancer (IARC) classification. Torrent is only recalling lots

of losartan containing products that contain Nitrosodiethylamine (NDEA) 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. Patients who are on Losartan 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.

Patients who are on losartan potassium and hydrocholothiazide 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.

The products subject to recall are listed below and packaged in bottles. The product can be identified by checking the product name, manufacturer details and batch or lot number on the bottle containing these products.

NDC	Manufacturer	Product Description	Lot/Batch	Expiration Date
13668-115-30	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,30count bottles	BO31C016	04/2019
13668-115-90	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,90count bottles	BO31C016	04/2019
13668-115-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles	4DK3C005	04/2019
13668-115-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles	4DK3C004	04/2019
13668-115-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles	4DU3C040	10/2019
13668-115-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles	4DU3E049	05/2021
13668-115-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 100mg,1000-count bottles	4DU3E050	05/2021
13668-409-30	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 50mg,30count bottles	4L67C035	10/2019
13668-409-90	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 50mg,90count bottles	4L67C035	10/2019
13668-409-90	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 50mg,90count bottles	4L67C036	10/2019
13668-409-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 50mg,1000-count bottles	4O50C005	11/2019

NDC	Manufacturer	Product Description	Lot/Batch	Expiration Date
13668-113-90	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 25mg,90count bottles	4O49C013	09/2019
13668-116-90	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM and HYDROCHOLOROTHIAZIDE TABLETS, USP 50mg/12.5 mg, 90 count bottles.	BP02C008	03/2019
13668-116-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM and HYDROCHOLOROTHIAZIDE TABLETS, USP 50mg/12.5 mg, 1000 count bottles.	BEF7D006	03/2020
13668-117-90	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM and HYDROCHOLOROTHIAZIDE TABLETS, USP 100 mg/12.5 mg, 90 count bottles.	BX35C020	05/2019
13668-117-90	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM and HYDROCHOLOROTHIAZIDE TABLETS, USP 100 mg/12.5 mg, 90 count bottles.	BX35C049	08/2019
13668-117-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM and HYDROCHOLOROTHIAZIDE TABLETS, USP 100 mg/12.5 mg, 1000 count bottles.	BX35C022	05/2019
13668-117-10	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM and HYDROCHOLOROTHIAZIDE TABLETS, USP 100 mg/12.5 mg, 1000 count bottles.	BX35C023	05/2019

Losartan potassium 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 associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, 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)** or 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/ucm628966.htm)**

Link to **Expanded Recall (/Safety/Recalls/ucm629261.htm)**

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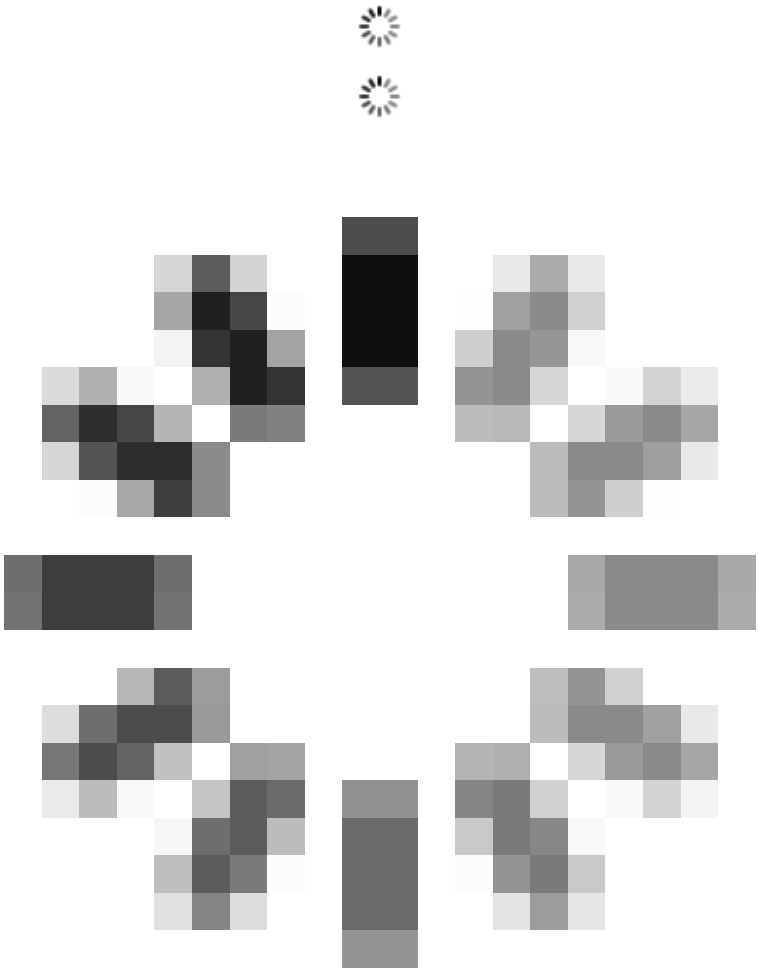
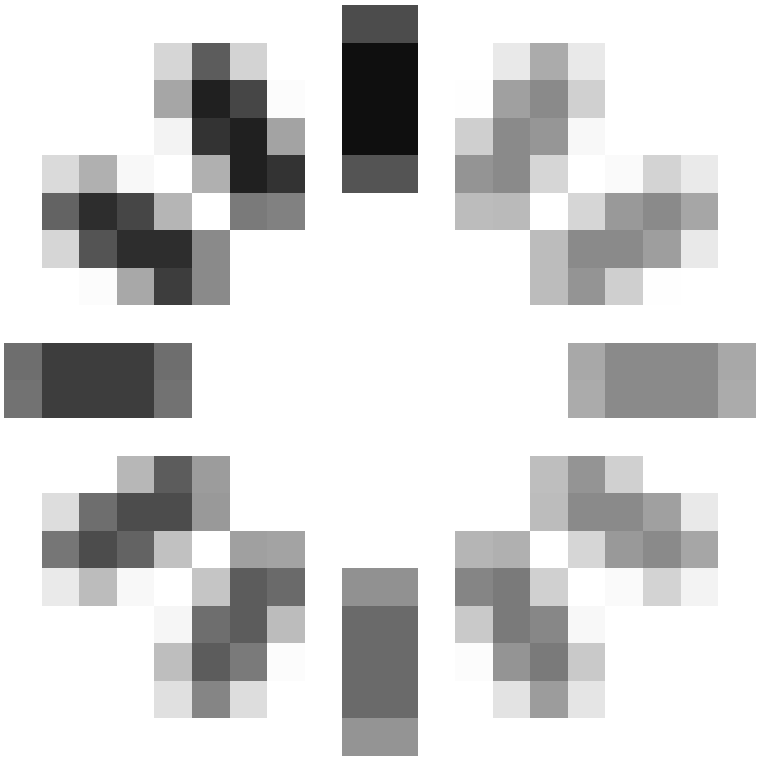
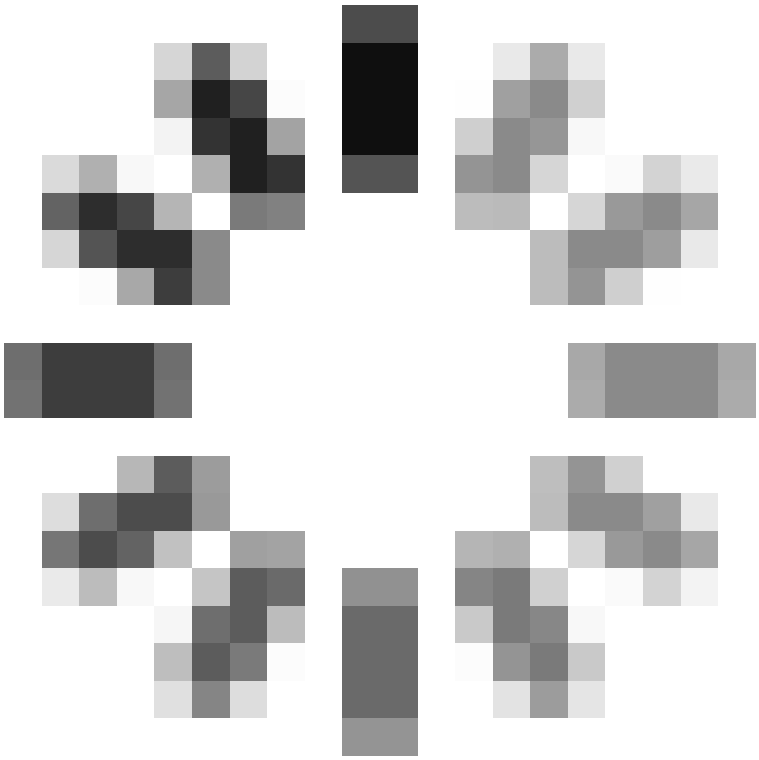
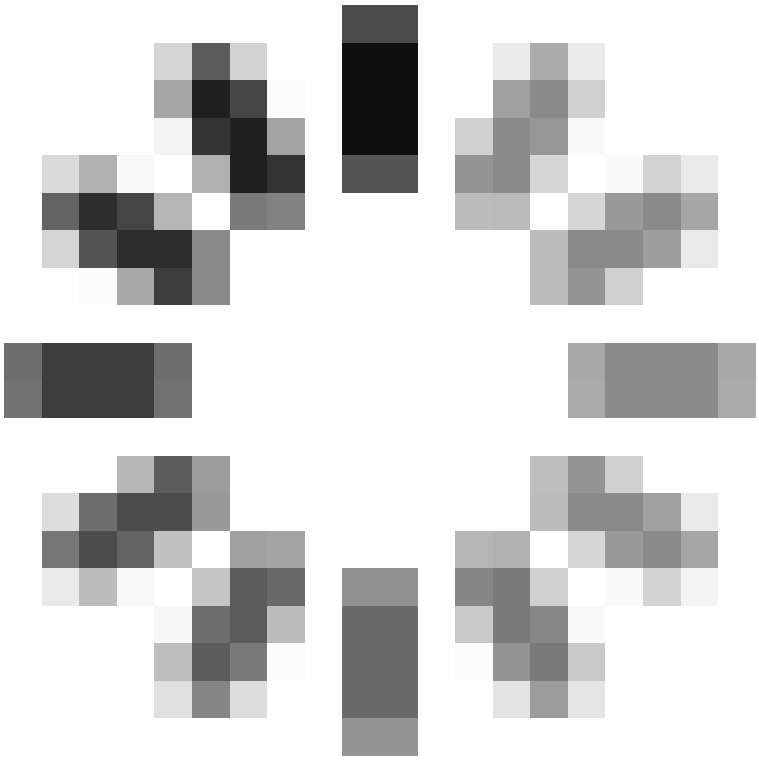
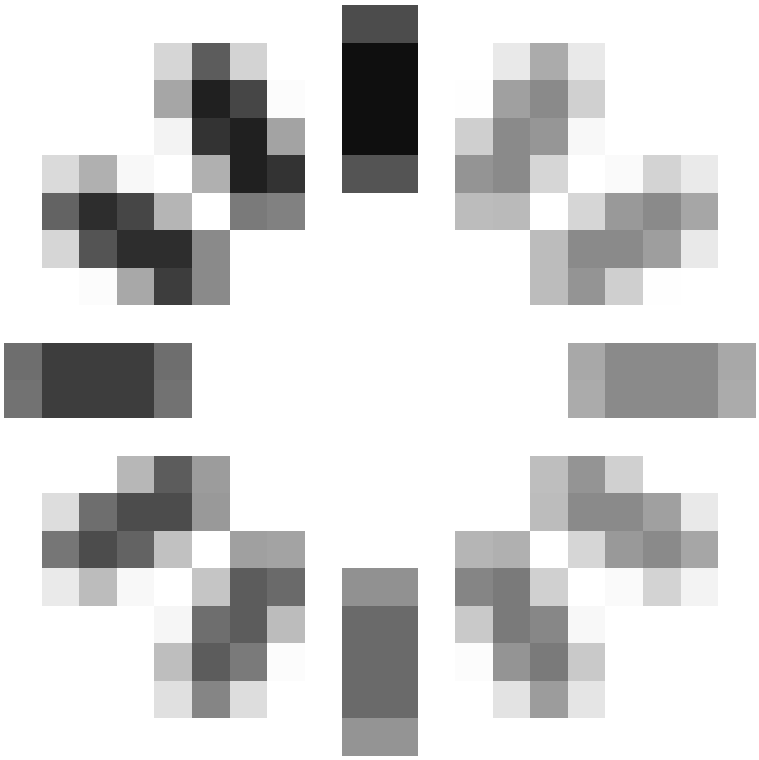
Product Photos

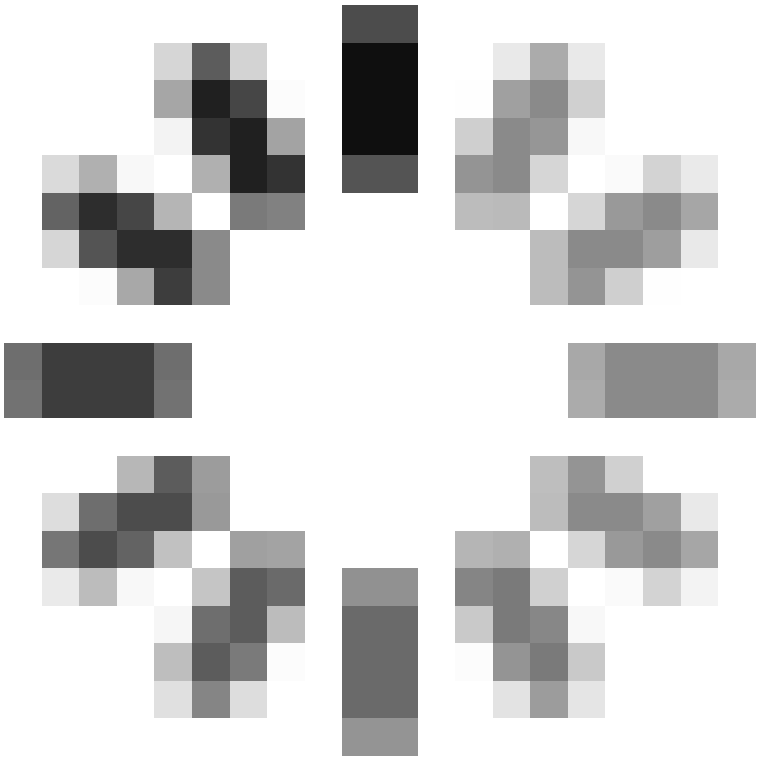












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