DOCTORS
HEALTHCARE PLANS, INC.

Drug recall notice for **Losartan Potassium tablets**

Torrent Pharmaceuticals Limited, makers of **Losartan Potassium tablets,** is recalling specific lots of Losartan Potassium tablets.

What your patients should know:

They may be able to get the same medicine that is not part of the recall or switch to another medicine. Please review treatment options and if a decision is made to switch to an alternative medicine, irbesartan, olmesartan and telmisartan are covered formulary options.

Please refer your patient to the FDA for the most current updates to this drug or have your patient ask their pharmacy for assistance.

https://www.fda.gov/Safety/Recalls/ucm628966.htm (original recall)
https://www.fda.gov/Safety/Recalls/ucm629261.htm (expanded recall)

To determine if your patient's medicine is impacted, check the product name, manufacturer name and NDC. If the information is not listed (NDC or lot number), please contact the pharmacy that filled the prescription.

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.

- **Online:** Complete and submit the report: www.fda.gov/medwatch/report.htm
- **Regular mail or fax:** Download form 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.

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Voluntary Recall Letter

Torrent Pharmaceuticals Limited is expanding its voluntary recall from 2 lots of Losartan potassium tablets USP to a total of 10 lots, 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. Torrent is only recalling lots of losartan-containing products that contain N-nitrosodiethylamine (NDEA) above the acceptable daily intake levels released by the FDA.

NDEA 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.

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.

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

NDC	Manufacturer	Product Description	Lot/Batch	Expiration Date
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
13668-113-90	Torrent Pharmaceuticals LTD	LOSARTAN POTASSIUM TAB, USP 25mg,90count bottles	4O49C013	09/2019

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