# UPDATED URGENT DRUG RECALL

## Date January 3, 2019

| Product Name | Description | NDCs | Batch/Lot |
|---|---|---|---|
| Losartan Potassium Tablets, USP | 25 mg | 13668-113-90 | See Attached List |
| Losartan Potassium Tablets, USP | 50 mg | 13668-409-30, 13668-409-90, 13668-409-10 | See Attached List |
| Losartan Potassium Tablets, USP | 100 mg | 13668-115-10, 13668-115-30, 13668-115-90 | See Attached List |

Dear Customer,

On Thursday December 20, 2018 Torrent Pharmaceuticals Limited initiated a voluntary recall to the consumer level of Losartan Potassium Tablets, USP. On January 3, 2019 we expanded the number of impacted batches adding Losartan Potassium Tablets, USP 25 mg and 50 mg tablets to the ongoing recall. The list below represents ALL LOTS of Torrent Losartan Potassium Tablets, USP that are part of this recall.

Our records indicate that you have purchased product from the subject batch/lot. This recall is being conducted with the knowledge of the Food and Drug Administration.

This recall is 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 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(s) identified below. In addition, if you may have further distributed this product, please identify your customers and notify them at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

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 Recall product, please return to Qualanex, LLC., using the Postage Paid Product Return label that will be provided 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 products and lots addressed in this notification. Only product from these batch/lot will be accepted under the terms of this recall.

- 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).
- If you have any general questions regarding the return of this product please contact Qualanex at 1-888-280-2040 (8:00 am-5:30 pm Eastern Time).

We regret any inconvenience and appreciate your immediate cooperation.

Bernadette Attinger
Senior Director, Regulatory Affairs

| NDC | Product Description | Lot/Batch | Expiration Date |
|---|---|---|---|
| 13668-115-30 | LOSARTAN POTASSIUM TAB, USP 100mg,30s | BO31C016 | 04/2019 |
| 13668-115-90 | LOSARTAN POTASSIUM TAB, USP 100mg,90s | BO31C016 | 04/2019 |
| 13668-115-10 | LOSARTAN POTASSIUM TAB, USP 100mg,1000s | 4DK3C005 | 04/2019 |
| 13668-115-10 | LOSARTAN POTASSIUM TAB, USP 100mg,1000s | 4DK3C004 | 04/2019 |
| 13668-115-10 | LOSARTAN POTASSIUM TAB, USP 100mg,1000s | 4DU3C040 | 10/2019 |
| 13668-115-10 | LOSARTAN POTASSIUM TAB, USP 100mg,1000s | 4DU3E049 | 05/2021 |
| 13668-115-10 | LOSARTAN POTASSIUM TAB, USP 100mg,1000s | 4DU3E050 | 05/2021 |
| 13668-409-30 | LOSARTAN POTASSIUM TAB, USP 50mg,30s | 4L67C035 | 10/2019 |
| 13668-409-90 | LOSARTAN POTASSIUM TAB, USP 50mg,90s | 4L67C035 | 10/2019 |
| 13668-409-90 | LOSARTAN POTASSIUM TAB, USP 50mg,90s | 4L67C036 | 10/2019 |
| 13668-409-10 | LOSARTAN POTASSIUM TAB, USP 50mg,1000s | 4O50C005 | 11/2019 |
| 13668-113-90 | LOSARTAN POTASSIUM TAB, USP 25mg,90s | 4O49C013 | 09/2019 |