

## Drug recall notice for **Losartan Potassium Tablets and Losartan Potassium Hydrochlorothiazide tablets**

Torrent Pharmaceuticals Limited is voluntarily recalling 60 lots of Losartan potassium tablets USP and 54 lots of 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 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.

### **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, candesartan, candesartan/hctz, irbesartan, irbesartan/hctz, olmesartan, olmesartan/hctz, telmisartan, telmisartan/hctz, valsartan, valsartan/hctz, 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/ucm632509.htm>

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](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.

H4140\_RXRECALLPROV\_C

## Voluntary Recall Letter:

Torrent Pharmaceuticals Limited is voluntarily recalling 60 lots of Losartan potassium tablets USP and 54 lots of 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 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 products subject to 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

<b>NDC</b>	<b>Finished Product Strength and Package Count</b>	<b>Batch Number</b>	<b>Expiration Date</b>
13668-113-90	Losartan Potassium Tablets, USP 25mg, 90 count	4DU1E005	1/31/2021
13668-113-90	Losartan Potassium Tablets, USP 25mg, 90 count	4DU1E006	1/31/2021
13668-113-90	Losartan Potassium Tablets, USP 25mg, 90 count	4DU1E008	1/31/2021
13668-113-10	Losartan Potassium Tablets, USP 25mg, 1000 count	4DU1E007	1/31/2021
13668-409-30	Losartan Potassium Tablets, USP 50mg, 30 count	4DU2D077	10/31/2020
13668-409-90	Losartan Potassium Tablets, USP 50mg, 90 count	4DU2D087	10/31/2020

<b>NDC</b>	<b>Finished Product Strength and Package Count</b>	<b>Batch Number</b>	<b>Expiration Date</b>
13668-409-90	Losartan Potassium Tablets, USP 50mg, 90 count	4DU2E023	1/31/2021
13668-409-90	Losartan Potassium Tablets, USP 50mg, 90 count	4DU2E024	1/31/2021
13668-409-90	Losartan Potassium Tablets, USP 50mg, 90 count	4DU2E026	1/31/2021
13668-409-90	Losartan Potassium Tablets, USP 50mg, 90 count	4DU2E027	1/31/2021
13668-409-90	Losartan Potassium Tablets, USP 50mg, 90 count	4DU2E028	1/31/2021
13668-409-90	Losartan Potassium Tablets, USP 50mg, 90 count	4DU2E029	1/31/2021
13668-409-90	Losartan Potassium Tablets, USP 50mg, 90 count	4DU2E020	1/31/2021
13668-409-90	Losartan Potassium Tablets, USP 50mg, 90 count	4O50E007	8/31/2021
13668-409-90	Losartan Potassium Tablets, USP 50mg, 90 count	4O50E008	8/31/2021
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D067	9/30/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D069	9/30/2020

<b>NDC</b>	<b>Finished Product Strength and Package Count</b>	<b>Batch Number</b>	<b>Expiration Date</b>
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D063	9/30/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D064	9/30/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D065	9/30/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D066	9/30/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D084	10/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D085	10/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D083	10/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D082	10/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D072	10/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D077	10/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D078	10/31/2020

<b>NDC</b>	<b>Finished Product Strength and Package Count</b>	<b>Batch Number</b>	<b>Expiration Date</b>
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D079	10/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D081	10/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D080	10/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D070	10/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D073	10/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D074	10/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D075	10/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D086	10/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D088	10/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D089	10/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E019	1/31/2021

<b>NDC</b>	<b>Finished Product Strength and Package Count</b>	<b>Batch Number</b>	<b>Expiration Date</b>
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E021	1/31/2021
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E022	1/31/2021
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E025	1/31/2021
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E032	2/28/2021
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E033	2/28/2021
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E034	2/28/2021
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E035	2/28/2021
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E036	2/28/2021
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E037	2/28/2021
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E038	2/28/2021
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E039	2/28/2021

<b>NDC</b>	<b>Finished Product Strength and Package Count</b>	<b>Batch Number</b>	<b>Expiration Date</b>
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E041	2/28/2021
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E103	6/30/2021
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E101	6/30/2021
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E102	6/30/2021
13668-115-90	Losartan Potassium Tablets, USP 100mg, 90 count	4DU3E014	1/31/2021
13668-115-90	Losartan Potassium Tablets, USP 100mg, 90 count	4DU3E015	1/31/2021
13668-115-90	Losartan Potassium Tablets, USP 100mg, 90 count	4DU3E065	7/31/2021
13668-115-10	Losartan Potassium Tablets, USP 100mg, 1000 count	4DU3D018	11/30/2020
13668-115-10	Losartan Potassium Tablets, USP 100mg, 1000 count	4DU3E062	6/30/2021
13668-115-10	Losartan Potassium Tablets, USP 100mg, 1000 count	4DU3E063	6/30/2021
13668-116-30	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 30 count	BEF7D017	6/30/2020

<b>NDC</b>	<b>Finished Product Strength and Package Count</b>	<b>Batch Number</b>	<b>Expiration Date</b>
13668-116-90	Losartan Potassium /Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	BEF7D010	4/30/2020
13668-116-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	BEF7D011	4/30/2020
13668-116-90	Losartan Potassium /Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	BEF7D018	6/30/2020
13668-116-90	Losartan Potassium / Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	BEF7D009	4/30/2020
13668-116-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	4P02E002	1/31/2021
13668-116-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	4P02E003	1/31/2021
13668-116-90	Losartan Potassium / Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	4P02E004	1/31/2021
13668-116-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 1000 count	BEF7D008	4/30/2020
13668-116-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 1000 count	BEF7D022	8/31/2020
13668-116-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 1000 count	BEF7D012	4/30/2020
13668-116-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 1000 count	BEF7D013	4/30/2020



<b>NDC</b>	<b>Finished Product Strength and Package Count</b>	<b>Batch Number</b>	<b>Expiration Date</b>
13668-116-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 1000 count	BEF7D049	11/30/2020
13668-116-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 1000 count	4P02E005	1/31/2021
13668-116-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 1000 count	4P02E006	1/31/2021
13668-117-30	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 30 count	BEF8D058	11/30/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D023	4/30/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D024	4/30/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D025	4/30/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D009	3/31/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D010	3/31/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D011	3/31/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D012	3/31/2020

<b>NDC</b>	<b>Finished Product Strength and Package Count</b>	<b>Batch Number</b>	<b>Expiration Date</b>
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D013	3/31/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D054	10/31/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D055	10/31/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D056	10/31/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D057	11/30/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D007	3/31/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D008	3/31/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D020	4/30/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D021	4/30/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D022	4/30/2020
13668-118-30	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 30 count	BEF6D038	4/30/2020

<b>NDC</b>	<b>Finished Product Strength and Package Count</b>	<b>Batch Number</b>	<b>Expiration Date</b>
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D030	4/30/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D031	4/30/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D047	7/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90count	BEF6D048	7/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D049	7/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D050	7/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D051	7/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D082	10/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D083	10/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D084	10/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D085	10/31/2020

NDC	Finished Product Strength and Package Count	Batch Number	Expiration Date
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D086	10/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D087	10/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	4P04E003	1/31/2021
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	4P04E004	1/31/2021
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	4P04E005	1/31/2021
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	4P04E006	1/31/2021
13668-118-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 1000 count	4P04E007	1/31/2021
13668-118-10	Losartan Potassium/Hydrochlorothiazide Tablets, USP 100mg/25mg, 1000 count	4P04E008	1/31/2021
13668-118-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 1000 count	4P04E009	1/31/2021

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

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### Product Photos





30 Tablets NDC 13668-409-30  
**Losartan Potassium  
Tablets USP**

**50 mg**

**PHARMACIST: PLEASE DISPENSE WITH ATTACHED  
PATIENT INFORMATION LEAFLET**



Manufactured by :  
TORRENT PHARMACEUTICALS LTD.  
Indrad-382 721, Dist. Mehsana, INDIA.

**Rx only**

For :  
TORRENT PHARMA INC.  
150 Allen Road, Suite 102  
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.

8045038

**Usual Dosage:**  
See accompanying prescribing information.  
Mfg. Lic. No. : G/926



N 3 13668-409-30 7

90 Tablets NDC 13668-409-90  
**Losartan Potassium  
Tablets USP**

**50 mg**

**PHARMACIST: PLEASE DISPENSE WITH ATTACHED  
PATIENT INFORMATION LEAFLET**



Manufactured by :  
TORRENT PHARMACEUTICALS LTD.  
Indrad-382 721, Dist. Mehsana, INDIA.

**Rx only**

For :  
TORRENT PHARMA INC.  
150 Allen Road, Suite 102  
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.

8045039

**Usual Dosage:**  
See accompanying prescribing information.  
Mfg. Lic. No. : G/926



N 3 13668-409-90 1

90 Tablets NDC 13668-113-90  
**Losartan Potassium  
Tablets USP**  
**25 mg**

PHARMACIST: PLEASE DISPENSE WITH ATTACHED  
PATIENT INFORMATION LEAFLET



Manufactured by:  
TORRENT PHARMACEUTICALS LTD.  
Indrad-382 721, Dist. Mehsana, INDIA.

**Rx only**

For:  
TORRENT PHARMA INC.  
150 Allen Road, Suite 102  
Basking Ridge, NJ 07920.

Each tablet contains 25 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.

8045036

**Usual Dosage:**  
See accompanying prescribing  
information.  
Mfg. Lic. No. : G/926



N 3 13668-113-90 7

1000 Tablets NDC 13668-113-10  
**Losartan Potassium  
Tablets USP**  
**25 mg**

PHARMACIST: PLEASE DISPENSE WITH PATIENT  
INFORMATION LEAFLET PROVIDED SEPARATELY



Manufactured by:  
TORRENT PHARMACEUTICALS LTD.  
Indrad-382 721, Dist. Mehsana, INDIA.

**Rx only**

For:  
TORRENT PHARMA INC.  
150 Allen Road, Suite 102  
Basking Ridge, NJ 07920.

Each tablet contains 25 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/926

8070934



N 3 13668-113-10 5

1000 Tablets NDC 13668-409-10  
**Losartan Potassium  
Tablets USP**  
**50 mg**

PHARMACIST: PLEASE DISPENSE WITH PATIENT  
INFORMATION LEAFLET PROVIDED SEPARATELY



Manufactured by:  
TORRENT PHARMACEUTICALS LTD.  
Indrad-382 721, Dist. Mehsana, INDIA.

**Rx only**

For:  
TORRENT PHARMA INC.  
150 Allen Road, Suite 102  
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/926

8045040



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



Manufactured by:  
TORRENT PHARMACEUTICALS LTD.  
Indrad-382 721, Dist. Mehsana, INDIA.

**Rx only**

For:  
TORRENT PHARMA INC.  
150 Allen Road, Suite 102  
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.

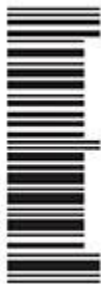
Dispense in a tight, light-resistant container with  
a child resistant closure.

**Usual Dosage:**

See accompanying prescribing information.

Mfg. Lic. No. : G-926

8045137



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



Manufactured by:  
TORRENT PHARMACEUTICALS LTD.  
Indrad-382 721, Dist. Mehsana, INDIA.

For:  
TORRENT PHARMA INC.  
150 Allen Road, Suite 102  
Basking Ridge, NJ 07920.

Rx only

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].

Protected from light.

Dispense in a tight, light-resistant container with a child-resistant closure.

Usual Dosage:

See accompanying prescribing information.

Mfg. Lic. No. : G-926

8045138



N  
3 13668-115-10 9





NDC 13668-116-30  
**LOSARTAN POTASSIUM  
and  
HYDROCHLOROTHIAZIDE  
Tablets, USP**

**50 mg/12.5 mg**

30 tablets

**Rx only**

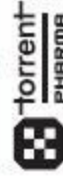
PHARMACIST : PLEASE DISPENSE WITH  
ATTACHED PATIENT INFORMATION SHEET.

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.



Mfg. Lic. No. : G/926

8045077

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



N 3 13668-116-30 4

NDC 13668-116-90  
**LOSARTAN POTASSIUM  
and  
HYDROCHLOROTHIAZIDE  
Tablets, USP**

**50 mg/12.5 mg**

90 tablets

**Rx only**

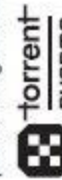
PHARMACIST : PLEASE DISPENSE WITH  
ATTACHED PATIENT INFORMATION SHEET.

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.



Mfg. Lic. No. : G/926

8045078

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



N 3 13668-116-90 8

NDC 13668-116-10  
**LOSARTAN POTASSIUM  
and  
HYDROCHLOROTHIAZIDE  
Tablets, USP**

**50 mg/12.5 mg**

1000 tablets

**Rx only**

PHARMACIST : PLEASE DISPENSE WITH  
PATIENT INFORMATION SHEET PROVIDED  
SEPARATELY.

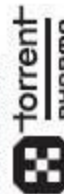
Each tablet contains 50 mg losartan potassium, USP  
and 12.5 mg hydrochlorothiazide, USP.

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.



Mfg. Lic. No. : G/926

8045079

Manufactured by :  
TORRENT PHARMACEUTICALS LTD.  
Indrad-382 721, Dist. Mehsana, INDIA.

For :  
TORRENT PHARMA INC.  
150 Allen Road, Suite 102, Basking Ridge, NJ 07920.



N 3 13668-116-10 6

NDC 13668-117-30  
**LOSARTAN POTASSIUM  
 and  
 HYDROCHLOROTHIAZIDE  
 Tablets, USP**

**100 mg/12.5 mg**

30 tablets

**Rx only**

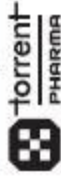
PHARMACIST : PLEASE DISPENSE WITH  
 ATTACHED PATIENT INFORMATION SHEET.

Each tablet contains 100 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.



Mfg. Lic. No.: G/926

8045080

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



N 3 13668-117-30 1

NDC 13668-117-90  
**LOSARTAN POTASSIUM  
 and  
 HYDROCHLOROTHIAZIDE  
 Tablets, USP**

**100 mg/12.5 mg**

90 tablets

**Rx only**

PHARMACIST : PLEASE DISPENSE WITH  
 ATTACHED PATIENT INFORMATION SHEET.

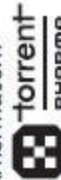
Each tablet contains 100 mg losartan potassium, USP and 12.5 mg hydrochlorothiazide, USP.

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.



Mfg. Lic. No.: G/926  
 8045081

Manufactured by:  
 TORRENT PHARMACEUTICALS LTD.  
 Indrad-382 721, Dist. Mehsana, INDIA.

For:  
 TORRENT PHARMA INC.  
 150 Allen Road, Suite 102, Basking Ridge, NJ 07920.



N 3 13668-117-90 5

NDC 13668-118-30  
**LOSARTAN POTASSIUM  
 and  
 HYDROCHLOROTHIAZIDE  
 Tablets, USP**

**100 mg/25 mg**

30 tablets

**Rx only**

PHARMACIST : PLEASE DISPENSE WITH  
 ATTACHED PATIENT INFORMATION SHEET.

Each tablet contains 100 mg losartan potassium, USP and 25 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.



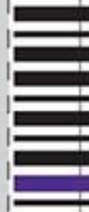
Mfg. Lic. No.: G/926

8045083

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



N 3 13668-118-30 8



NDC 13668-118-90  
**LOSARTAN POTASSIUM  
 and  
 HYDROCHLOROTHIAZIDE  
 Tablets, USP**

**100 mg/25 mg**

90 tablets

**Rx only**

PHARMACIST : PLEASE DISPENSE WITH  
 ATTACHED PATIENT INFORMATION SHEET.

Each tablet contains 100 mg losartan potassium, USP and 25 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.



Mfg. Lic. No.: G/926

8045084

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



N 3 13668-118-90 2



NDC 13668-118-10

**LOSARTAN POTASSIUM  
and  
HYDROCHLOROTHIAZIDE  
Tablets, USP**

**100 mg/25 mg**

1000 tablets

**Rx only**

**PHARMACIST : PLEASE DISPENSE WITH  
PATIENT INFORMATION SHEET PROVIDED  
SEPARATELY.**

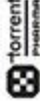
Each tablet contains 100 mg losartan potassium, USP  
and 25 mg hydrochlorothiazide, USP.

Store at 20° to 25° C (68° to 77°F) (See USP  
controlled room temperature).

Protect from light.

Dispense in a light, light-resistant container with a  
child-resistant closure.

**Usual Dosage:** See accompanying prescribing  
information.



Mfg. Lic. No. : 01926

Manufactured by :  
TORRENT PHARMACEUTICALS LTD.  
Indrad-382 721, Dist. Mehsana, INDIA.

For :  
TORRENT PHARMA INC.  
150A New Road, Suite 102, Basking Ridge, NJ 07920.

8045085



N

3 13668-118-10 0

