Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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

For Immediate Release

April 18, 2019

Contact

Consumers

1-800-912-9561
Medinfo.Torrent@apcerls.com (mailto:Medinfo.Torrent@apcerls.com)

Announcement

View Product Photos

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 found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited.

The Recall is expanded to include an additional 36 lots of Losartan potassium Tablets USP and 68 lots of Losartan Potassium/Hydrochlorothiazide Tablets, USP

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 product/lots included in the expanded recall are listed below in red. 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	Finished Product Strength and Package Count	Batch Number	Expiration Date
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
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

NDC	Finished Product Strength and Package Count	Batch Number	Expiration Date
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
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
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D079	10/31/2020

NDC	Finished Product Strength and Package Count	Batch Number	Expiration Date
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
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

NDC	Finished Product Strength and Package Count	Batch Number	Expiration Date
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
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
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

NDC	Finished Product Strength and Package Count	Batch Number	Expiration Date
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
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

NDC	Finished Product Strength and Package Count	Batch Number	Expiration Date
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
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

NDC	Finished Product Strength and Package Count	Batch Number	Expiration Date
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
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
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
13668-113-90	Losartan Potassium Tablets, USP 25mg, 90 count	BDK1C003	7/31/2019
13668-113-10	Losartan Potassium Tablets, USP 25mg, 1000 count	BDK1C002	7/31/2019
13668-113-10	Losartan Potassium Tablets, USP 25mg, 1000 count	4DU1D004	12/31/2019
13668-113-10	Losartan Potassium Tablets, USP 25mg, 1000 count	4DU1D005	12/31/2019
13668-113-10	Losartan Potassium Tablets, USP 25mg, 1000 count	4DU1D006	12/31/2019
13668-409-90	Losartan Potassium Tablets, USP 50mg, 90 count	4DU2D005	12/31/2019
13668-409-90	Losartan Potassium Tablets, USP 50mg, 90 count	4DU2D006	12/31/2019
13668-409-90	Losartan Potassium Tablets, USP 50mg, 90 count	4DU2D026	3/31/2020
13668-409-90	Losartan Potassium Tablets, USP 50mg, 90 count	4DU2D027	3/31/2020

NDC	Finished Product Strength and Package Count	Batch Number	Expiration Date
13668-409-90	Losartan Potassium Tablets, USP 50mg, 90 count	4DU2D029	3/31/2020
13668-409-90	Losartan Potassium Tablets, USP 50mg,90 count	4DU2E007	12/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D040	8/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D041	8/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D042	8/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D017	2/29/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D025	3/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D028	3/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D045	8/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D046	8/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D047	8/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2D048	8/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E042	2/28/2021
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	4DU2E044	2/28/2021
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	BDK2E001	12/31/2020
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	BDK2E012	8/31/2021
13668-409-10	Losartan Potassium Tablets, USP 50mg, 1000 count	BDK2E013	8/31/2021
13668-115-90	Losartan Potassium Tablets, USP 100mg, 90 count	4DU3E016	1/31/2021

NDC	Finished Product Strength and Package Count	Batch Number	Expiration Date
13668-115-10	Losartan Potassium Tablets, USP 100mg, 1000 count	4DU3E017	1/31/2021
13668-115-10	Losartan Potassium Tablets, USP 100mg, 1000 count	4DU3E019	2/28/2021
13668-115-10	Losartan Potassium Tablets, USP 100mg, 1000 count	4DU3C012	7/31/2019
13668-115-10	Losartan Potassium Tablets, USP 100mg, 1000 count	4DU3C015	8/31/2019
13668-115-10	Losartan Potassium Tablets, USP 100mg, 1000 count	4DU3C016	8/31/2019
13668-115-10	Losartan Potassium Tablets, USP 100mg, 1000 count	4DU3C017	8/31/2019
13668-115-10	Losartan Potassium Tablets, USP 100mg, 1000 count	4DU3C031	9/30/2019
13668-115-10	Losartan Potassium Tablets, USP 100mg, 1000 count	4DU3D007	1/31/2020
13668-115-10	Losartan Potassium Tablets, USP 100mg, 1000 count	4DU3D008	1/31/2020
13668-116-30	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 30 count	BP02D005	12/31/2019
13668-116-30	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 30 count	BP02C051	10/31/2019
13668-116-30	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 30 count	BEF7D047	11/30/2020
13668-116-90	Losartan Potassium /Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	BP02D006	12/31/2019
13668-116-90	Losartan Potassium /Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	BP02D007	12/31/2019
13668-116-90	Losartan Potassium /Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	BP02D012	1/31/2020
13668-116-90	Losartan Potassium /Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	BEF7D003	3/31/2020
13668-116-90	Losartan Potassium /Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	BP02C050	10/31/2019
13668-116-90	Losartan Potassium /Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	BEF7D026	8/31/2020

NDC	Finished Product Strength and Package Count	Batch Number	Expiration Date
13668-116-90	Losartan Potassium /Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	BEF7D027	8/31/2020
13668-116-90	Losartan Potassium /Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	BEF7D028	8/31/2020
13668-116-90	Losartan Potassium /Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	BEF7D045	11/30/2020
13668-116-90	Losartan Potassium /Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	BEF7D046	11/30/2020
13668-116-90	Losartan Potassium /Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 90 count	BEF7E005	1/31/2021
13668-116-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 1000 count	BEF7D005	3/31/2020
13668-116-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 1000 count	BEF7D029	8/31/2020
13668-116-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 1000 count	BEF7D030	8/31/2020
13668-116-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 1000 count	BEF7D048	11/30/2020
13668-116-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 1000 count	BEF7E001	12/31/2020
13668-116-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 1000 count	BEF7E002	12/31/2020
13668-116-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 1000 count	BEF7E003	12/31/2020
13668-116-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 1000 count	BEF7E004	12/31/2020
13668-116-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 1000 count	BP02C051	10/31/2019
13668-116-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 50mg/12.5mg, 1000 count	BP02C052	10/31/2019
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D060	11/30/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D061	11/30/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D062	11/30/2020

NDC	Finished Product Strength and Package Count	Batch Number	Expiration Date
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D063	11/30/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BX35D024	1/31/2020
13668-117-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 90 count	BEF8D064	11/30/2020
13668-117-10	Losartan Potassium /Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 1000 count	BEF8D059	11/30/2020
13668-117-10	Losartan Potassium /Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 1000 count	BEF8E004	1/31/2021
13668-117-10	Losartan Potassium /Hydrochlorothiazide Tablets, USP 100mg/12.5mg, 1000 count	BEF8E005	1/31/2021
13668-118-30	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 30 count	BEF6D054	8/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D100	11/30/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D101	11/30/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D102	11/30/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6E001	12/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6E002	12/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6E003	12/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6E004	12/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6E008	12/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6E009	12/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6E010	12/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6E011	12/31/2020

NDC	Finished Product Strength and Package Count	Batch Number	Expiration Date
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6E012	12/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BP04D012	12/31/2019
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BP04D013	12/31/2019
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BP04C092	10/31/2019
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D012	3/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D013	3/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D060	9/30/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D061	9/30/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D063	9/30/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D076	10/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D077	10/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D078	10/31/2020
13668-118-90	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 90 count	BEF6D079	10/31/2020
13668-118-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 1000 count	BP04C094	10/31/2019
13668-118-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 1000 count	BEF6D096	11/30/2020
13668-118-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 1000 count	BEF6D097	11/30/2020
13668-118-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 1000 count	BEF6D098	11/30/2020
13668-118-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 1000 count	BEF6D099	11/30/2020

NDC	Finished Product Strength and Package Count	Batch Number	Expiration Date
13668-118-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 1000 count	BEF6E005	12/31/2020
13668-118-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 1000 count	BEF6E006	12/31/2020
13668-118-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 1000 count	BP04D016	2/29/2020
13668-118-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 1000 count	BP04D017	2/29/2020
13668-118-10	Losartan Potassium/ Hydrochlorothiazide Tablets, USP 100mg/25mg, 1000 count	BP04D018	2/29/2020

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 found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited.

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: (http://www.fda.gov/medwatch/report.htm)www.fda.gov/medwatch/report.htm (http://www.fda.gov/medwatch/report.htm)**

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

Link to **Original Recall (/Safety/Recalls/ucm628966.htm)**

Link to **1st Expansion Recall (/Safety/Recalls/ucm629261.htm)**

Link to **2nd Expansion Recall (/Safety/Recalls/ucm629693.htm)**

Link to **3rd Expansion Recall (/Safety/Recalls/ucm632509.htm)**

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