



## Torrent – Recall of losartan-containing products

- On March 1, 2019, the [FDA announced](#) the voluntary, consumer-level recall of several lots of Torrent Pharmaceuticals’ [losartan](#) and [losartan/hydrochlorothiazide](#) (HCTZ) tablets due to the detection of trace amounts of an unexpected impurity, N-Methylnitrosobutyric acid (NMBA), found in an active pharmaceutical ingredient manufactured by Hetero Labs Limited.
  - Torrent is only recalling lots of losartan-containing products that contain NMBA above the acceptable daily intake levels released by the FDA.
- NMBA is a potential human carcinogen. To date, Torrent has not received any reports of adverse events related to this recall.
  - Refer to the [FDA site](#) for updates regarding angiotensin II receptor blocker recalls.
- The recalled products are listed below:

Product Description	NDC#	Lot# (Expiration Date)
Losartan Tablets 25 mg	13668-113-90	4DU1E005 (1/31/2021); 4DU1E006(1/31/2021); 4DU1E008 (1/31/2021)
	13668-113-10	4DU1E007 (1/31/2021)
Losartan Tablets 50 mg	13668-409-30	4DU2D077 (10/31/2020)
	13668-409-90	4DU2D087 (10/31/2020); 4DU2E023 (1/31/2021); 4DU2E024 (1/31/2021); 4DU2E026 (1/31/2021); 4DU2E027 (1/31/2021); 4DU2E028 (1/31/2021); 4DU2E029 (1/31/2021); 4DU2E020 (1/31/2021); 4O50E007 (8/31/2021); 4O50E008 (8/31/2021)
	13668-409-10	4DU2D067 (9/30/2020); 4DU2D069 (9/30/2020); 4DU2D063 (9/30/2020); 4DU2D064 (9/30/2020); 4DU2D065 (9/30/2020); 4DU2D066 (9/30/2020); 4DU2D084 (10/31/2020); 4DU2D085 (10/31/2020); 4DU2D083 (10/31/2020); 4DU2D082 (10/31/2020); 4DU2D072 (10/31/2020); 4DU2D077 (10/31/2020); 4DU2D078 (10/31/2020); 4DU2D079 (10/31/2020); 4DU2D081 (10/31/2020); 4DU2D080 (10/31/2020); 4DU2D070 (10/31/2020);

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		4DU2D073 (10/31/2020); 4DU2D074 (10/31/2020); 4DU2D075 (10/31/2020); 4DU2D086 (10/31/2020); 4DU2D088 (10/31/2020); 4DU2D089 (10/31/2020); 4DU2E019 (1/31/2021); 4DU2E021 (1/31/2021); 4DU2E022 (1/31/2021); 4DU2E025 (1/31/2021); 4DU2E032 (2/28/2021); 4DU2E033 (2/28/2021); 4DU2E034 (2/28/2021); 4DU2E035 (2/28/2021); 4DU2E036 (2/28/2021); 4DU2E037 (2/28/2021); 4DU2E038 (2/28/2021); 4DU2E039 (2/28/2021); 4DU2E041 (2/28/2021); 4DU2E103 (6/30/2021); 4DU2E101 (6/30/2021); 4DU2E102 (6/30/2021)
Losartan Tablets 100 mg	13668-115-90	4DU3E014 (1/31/2021); 4DU3E015 (1/31/2021); 4DU3E065 (7/31/2021)
	13668-115-10	4DU3D018 (11/30/2020); 4DU3E062 (6/30/2021); 4DU3E063 (6/30/2021)
Losartan/HCTZ Tablets 50 mg/12.5 mg	13668-116-30	BEF7D017 (6/30/2020)
	13668-116-90	BEF7D010 (4/30/2020); BEF7D011 (4/30/2020); BEF7D018 (6/30/2020); BEF7D009 (4/30/2020); 4P02E002 (1/31/2021); 4P02E003 (1/31/2021); 4P02E004 (1/31/2021)
	13668-116-10	BEF7D008 (4/30/2020); BEF7D022 (8/31/2020); BEF7D012 (4/30/2020); BEF7D013 (4/30/2020); BEF7D049 (11/30/2020); 4P02E005 (1/31/2021); 4P02E006 (1/31/2021)
Losartan/HCTZ Tablets 100 mg/12.5 mg	13668-117-30	BEF8D058 (11/30/2020)
	13668-117-90	BEF8D023 (4/30/2020); BEF8D024 (4/30/2020); BEF8D025 (4/30/2020); BEF8D009 (3/31/2020); BEF8D010 (3/31/2020); BEF8D011 (3/31/2020); BEF8D012 (3/31/2020); BEF8D013 (3/31/2020); BEF8D054 (10/31/2020); BEF8D055 (10/31/2020); BEF8D056 (10/31/2020); BEF8D057 (11/30/2020); BEF8D007 (3/31/2020); BEF8D008 (3/31/2020);

		BEF8D020 (4/30/2020); BEF8D021 (4/30/2020); BEF8D022 (4/30/2020)
Losartan/HCTZ Tablets 100 mg/25 mg	13668-118-30	BEF6D038 (4/30/2020)
	13668-118-90	BEF6D030 (4/30/2020); BEF6D031 (4/30/2020); BEF6D047 (7/31/2020); BEF6D048 (7/31/2020); BEF6D049 (7/31/2020); BEF6D050 (7/31/2020); BEF6D051 (7/31/2020); BEF6D082 (10/31/2020); BEF6D083 (10/31/2020); BEF6D084 (10/31/2020); BEF6D085 (10/31/2020); BEF6D086 (10/31/2020); BEF6D087 (10/31/2020); 4P04E003 (1/31/2021); 4P04E004 (1/31/2021); 4P04E005 (1/31/2021); 4P04E006 (1/31/2021)
	13668-118-10	4P04E007 (1/31/2021); 4P04E008 (1/31/2021); 4P04E009 (1/31/2021)

- Losartan and losartan/HCTZ tablets are used for the treatment of hypertension (HTN) and to reduce the risk of stroke in patients with HTN and left ventricular hypertrophy. Losartan tablets are also used for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria (urinary albumin to creatinine ratio  $\geq$  300 mg/g) in patients with type 2 diabetes and a history of HTN.
- Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on a losartan-containing product should continue taking their medication, as the risk of harm to a patient's health may be higher if the treatment is stopped immediately without any alternative treatment.
- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled losartan-containing product.
- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately.
- For more information regarding this recall, contact Torrent at **1-800-912-9561** or Qualanex (appointed company for Torrent Pharmaceuticals) at **1-888-280-2040**.



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