

Torrent – Recall of losartan/hydrochlorothiazide

- On January 22, 2019, [Torrent announced](#) an expansion of their voluntary, consumer-level recall of losartan tablets to include several lots of [losartan/hydrochlorothiazide \(HCTZ\)](#) tablets due to the detection of trace amounts of an unexpected impurity, identified as N-nitrosodiethylamine (NDEA), found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs.
 - Torrent initially announced a consumer-level recall of losartan on December 20, 2018. The recall was then expanded on January 3, 2019 to include additional lots of losartan.
- 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 classification.
 - Refer to the [FDA site](#) for updates regarding angiotensin II receptor blocker recalls.
- The products included in the expanded recall are listed below:

Product Description	NDC#	Lot# (Expiration Date)
Losartan/HCTZ 50/12.5 mg tablets	13668-116-90	BP02C008 (3/2019)
	13668-116-10	BEF7D006 (3/2020)
Losartan/HCTZ 100/12.5 mg tablets	13668-117-90	BX35C020 (5/2019); BX35C049 (8/2019)
	13668-117-10	BX35C023 (5/2019); BX35C022 (5/2019)

- 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.
- Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on losartan/HCTZ 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/HCTZ.
- 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**.