

Legacy Pharmaceutical Packaging – Recall of Iosartan

- On March 15 2019, Legacy Pharmaceutical Packaging announced_two voluntary, consumer-level recalls (<u>Torrent</u>, <u>Camber</u>) of some lots of <u>losartan</u> tablets due to the detection of trace amounts of an unexpected impurity, N-Nitroso N-Methyl 4-amino butyric acid (NMBA), a possible process impurity or contaminant in an active pharmaceutical ingredient, manufactured by Hetero Labs Limited.
- Legacy Pharmaceutical Packaging is a repackager for Camber and Torrent.
- NMBA is a potential human carcinogen.
 - Refer to the <u>FDA site</u> for updates regarding angiotensin II receptor blocker recalls.
- The recalled tablets are listed below:

Product Description	NDC#	Lot# (Expiration Date)
Losartan 25 mg tablets	68645-577-54	180952 (10/2019);180953 (12/2019); 181086 (09/2019); 181572 (01/2020)
Losartan 50 mg tablets	68645-578-54	180921 (09/2019); 180922 (10/2019); 180923 (11/2019); 180924 (11/2019); 181118 (11/2019); 181119 (10/2019); 181407 (11/2019); 181408 (12/2019); 181573 (02/2020); 181725 (02/2020); 181726 (02/2020); 181948 (03/2020); 181960 (02/2020); 182385 (03/2020); 182386 (03/2020); 182387 (03/2020)
	68645-494-54	180190 (10/2020); 180191 (10/2020); 181597 (02/2021)
Losartan 100 mg tablets	68645-579-54	180886 (11/2019); 180887 (12/2019); 180888 (12/2019); 180905 (12/2019); 181123 (09/2019); 181124 (10/2019); 181125 (08/2019); 181351 (11/2019); 181352 (12/2019); 181551 (11/2019); 181628 (06/2020); 181629 (06/2020); 181727 (06/2020); 181728 (06/2020); 181890 (03/2020); 181891 (06/2020); 181897 (06/2020); 182114 (03/2020); 182119 (06/2020); 182120 (06/2020)

Losartan is 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 ≥ 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 losartan 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.
- 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 Stericycle (appointed company for Camber repackaged products) at 1-888-275-0506 or Inmar (appointed company for Torrent repackaed products) 1-877-538-8443.



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