



## Legacy Pharmaceutical Packaging – Recall of losartan

- On April 24, 2019, [Legacy Pharmaceutical Packaging announced](#) an expansion to a consumer-level recall of 3 repackaged lots of [losartan](#) 50 mg tablets to include one additional lot.
- This recall was prompted due to Torrent issuing a voluntary nationwide recall of losartan tablets due to the detection of trace amounts of 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. NMBA is a potential human carcinogen.
  - This is an expansion to the recall that Legacy announced on [March 25, 2019](#).
  - Refer to the [FDA site](#) for updates regarding angiotensin II receptor blocker recalls.
- The expanded recall includes the product listed below:

Product Description	NDC#	Lot# (Expiration Date)
Losartan 50 mg tablets	68645-494-54	181598 (2/2021)

- Losartan 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 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 Inmar (appointed company for Legacy) at
- 1-877-538-8443.



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