Major – Recall of Losartan

- On January 10, 2019, Major announced a voluntary recall of one lot of losartan 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.

- 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 recalled product is listed below:

Product Description	NDC#	Lot# (Expiration Date)
Losartan 50 mg unit dose tablets	0904-6390-61	R-00474 (7/2019)

- Losartan tablets are used for the treatment of hypertension (HTN); to reduce the risk of stroke in patients with HTN and left ventricular hypertrophy; and 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 Torrent (manufacturer for Major) at **1-800-912-9561** or Stericycle at **1-877-220-4728** for general questions regarding return of the product. For all other questions, contact Major at **1-800-616-2471**.