AvKARE – Recall of losartan

- On April 23, 2019, AvKARE announced an expansion to the voluntary, consumer-level recall of some lots of losartan 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.
    - This is an expansion to the recall that AvKARE announced on March 4, 2019.
- NMBA is a potential human carcinogen.
    - Refer to the FDA site for updates regarding angiotensin II receptor blocker recalls.
- The expanded recall includes the products listed below:

Product Description	NDC#	Lot# (Expiration Date)
Losartan 25 mg tablets	50268-516-15	19554 (4/2019)
Losartan 50 mg tablets	50268-517-15	20121 (6/2019)

- 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 ≥ 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 AvKARE at **1-931-292-6222**.