Vivimed – Recall of losartan

- On May 3, 2019, Vivimed announced a voluntary consumer-level recall of 19 lots of losartan tablets due to the detection of an impurity, N-Nitroso-N-methyl-4-aminobutyric acid (NMBA), that is above the FDA's interim acceptable exposure limit of 9.82 ppm.
    - Based on the available information, the risk of developing cancer in a few patients following long-term use of the product containing high levels of the impurity NMBA cannot be ruled out.
    - This product was made by Vivimed and distributed by Heritage Pharmaceuticals.
- Refer to the FDA site for updates regarding angiotensin II receptor blocker recalls.
- The recall includes the products listed below:

Product Description	NDC#	Lot# (Expiration Date)
Losartan 25 mg tablets	23155-644-09	CLO17006A (Nov-19)
Losartan 50 mg tablets	23155-645-09	CLO17009B (Nov-19), CLO17010A (Nov-19), CLO18023A (Apr-20)
	23155-645-10	CLO17007A (Nov-19), CLO17008A (Nov-19), CLO17009A (Nov-19)
Losartan 100 mg tablets	23155-646-09	CLO17012A (Nov-19), CLO17013A (Nov-19), CLO18002A (Jan-20), CLO18020A (Apr-20), CLO18021A (Apr-20), CLO18022A (Apr-20)
	23155-646-10	CLO17014A (Dec-19), CLO17015A (Jan-20), CLO17016A (Jan-20), CLO17017A (Jan-20), CLO18001A (Jan-20), CLO18002B (Jan-20)

- 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 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.

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- Anyone with an existing inventory of the recalled product should stop use and distribution, and quarantine the product immediately.