Teva – Recall of losartan

- On June 11, 2019, the FDA announced a consumer-level recall of Teva's 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.
    - This recall is an expansion to Teva's recall of losartan that was originally initiated on April 25, 2019.
- The source of the NMBA impurity was detected in one lot of active pharmaceutical ingredient, manufactured by Hetero Labs Limited, which was used in the manufacturing of the six bulk lots of these drug products.
- Refer to the FDA site for updates regarding angiotensin II receptor blocker recalls.
- The bulk recalled lots were sold exclusively to Golden State Medical Supply. Golden State Medical Supply packaged these products under its own label and distributed retail bottles of 30, 90 and 1000 tablets.

Product Description	NDC#	Lot# (Expiration Date)
Losartan 50 mg tablets	60429-317-10	GS017387 (01/2020)
	60429-317-90	GS017651 (01/2020)
Losartan 100 mg tablets	60429-318-90	GS017042 (01/2020); GS017043 (01/2020); GS017044 (01/2020); GS017541 (01/2020)

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

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- For more information regarding this recall, contact Inmar (appointed company for Teva) by phone at **1-877-789-2065** or by email at **tevarecalls@inmar.com**; or Golden State Medical Supply at **1-800-284-8633** or by email at **recalls@gsms.us**.