Teva – Recall of losartan

- On April 29, 2019, the FDA announced a voluntary, patient-level recall of Teva's losartan tablets due to the detection of an impurity, N-Nitroso-N-methyl-4-aminobutyric acid (NMBA), found in six lots of active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited that is above the FDA's interim acceptable exposure limit of 9.82 ppm.

- The finished product lots were sold by Teva in bulk containers exclusively to Golden State Medical Supply (GSMS). GSMS packaged this bulk product into 44 finished products lots under its own label and distributed them in retail bottles of 30, 90, and 1000 tablets.

    — 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 Tablets 25 mg	60429-316-10	GS014817 (06/2019); GS015204 (06/2019); GS018318 (02/2020); GS017342 (02/2020); GS017808 (02/2020)
	60429-316-30	GS017981 (02/2020); GS016958 (02/2020); GS017341 (02/2020)
	60429-316-90	GS015172 (06/2019); GS017634 (02/2020); GS017653 (02/2020); GS017980 (02/2020); GS016726 (02/2020); GS017045 (02/2020); GS017276 (02/2020)
Losartan Tablets 100 mg	60429-318-10	GS014054 (06/2019); GS016338 (12/2019); GS016341 (01/2020); GS016342 (01/2020); GS016343 (01/2020); GS016344 (01/2020); GS016345 (01/2020); GS016539 (01/2020); GS016969 (01/2020); GS016973 (01/2020); GS017337 (01/2020); GS018524 (02/2020)

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	60429-318-90	GS014045 (06/2019); GS014305 (06/2019); GS014044 (06/2019); GS016535 (01/2020); GS016524 (01/2020); GS017384 (02/2020); GS017385 (01/2020); GS017539 (01/2020); GS017540 (01/2020); GS017543 (01/2020); GS017542 (01/2020); GS017984 (02/2020); GS017985 (02/2020); GS017986 (02/2020); GS018263 (02/2020); GS018264 (02/2020); GS018265 (02/2020)

- 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.

- To date, Teva has not received any reports of adverse events related to the recalled lots.

- 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 Teva at **1-888-838-2872**. Patients wishing to return product may contact Inmar (appointed company for Teva) at **1-877-789-2065** to obtain instructions and a return kit for returning their medication.