

June 17, 2019

COM-2019-025

Recall: Teva Expands Losartan Nationwide Recall Sold to Golden State Medical Supply Inc.

Dear provider of pharmaceutical services,

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform you that on June 11, 2019 the US Food and Drug Administration (FDA) issued a statement notifying that Teva Pharmaceuticals, has expanded its voluntary consumer-level recall originally initiated on April 25, 2019 for losartan 50mg and 100mg tablets. This time applies to lots sold to Golden State Medical Supply, Inc. The recall was made due to the detection of an impurity: N-Nitroso-N-methyl-4-aminobutyric acid (NMBA). The affected lots by the recall is detailed on Table 1.

NDC	Product	Affected Lot	Expiration date
60429-317-10	LOSARTAN POTASSIUM 50 mg TABLETS, USP 1000 tablets/bottle	GS017387	01/2020
60429-317-90	LOSARTAN POTASSIUM 50 mg TABLETS 90 tablets/bottle	GS017651	01/2020
60429-317-30	LOSARTAN POTASSIUM 50 mg TABLETS 30 tablets/bottle	GS017479	01/2020
60429-318-90	LOSARTAN POTASSIUM 100 mg TABLETS 90 tablets/bottle	GS017042	01/2020
60429-318-90	LOSARTAN POTASSIUM 100 mg TABLETS 90 tablets/bottle	GS017043	01/2020
60429-318-90	LOSARTAN POTASSIUM 100 mg TABLETS, USP 90 tablets/bottle	GS017044	01/2020
60429-318-90	LOSARTAN POTASSIUM 100 mg TABLETS, USP 90 tablets/bottle	GS017541	01/2020

Table 1: Affected Product of Losartan Potassium to 50 mg and 100 mg Tablets





The Pharmacy must:

- 1. Identify if they have the product in inventory and immediately stop using and dispensing the product.
- 2. Contact all members that in the previous 90 days received the recalled medication and advised them to talk to their doctor. Patients should not discontinue taking the medication without a doctor's permission.
- **3.** Contact information:
 - Patients who wants to return the product may contact: Inmar at 877-789-2065 (Hours of operation: 9 am to 5 pm Eastern Time, Monday – Friday) or email Inmar at: <u>tevarecalls@inmar.com</u>.
 - b. Customers of Golden State Medical Supply, Inc. may contact Inmar at: Call: (800) 284-8633, ext. 215, Fax: (805) 437-7582, Email: <u>recalls@gsms.us</u>

For additional information visit:

https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/teva-pharmaceuticalsusa-inc-expands-voluntary-nationwide-recall-losartan-potassium-50-mg-and-100-mg

Clinical Pharmacy Department

