April 29, 2019

COM-2019-018

Recall of Losartan Potassium 25 mg and 100 mg Tablets USP, Sold Exclusively to Golden State Medical Supply

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 April 26, 2019 the US Food and Drug Administration (FDA) issued a statement notifying that Teva Pharmaceuticals USA Inc. initiated a voluntary recall of 35 lots of bulk losartan potassium USP tablets (6 lots of 25 mg and 29 lots of 100 mg). This recall is due to an impurity, N-Nitroso-N-methyl-4-aminobutyric acid (NMBA), found in 6 lots of active pharmaceutical ingredient manufactured by Hetero Labs Limited that is above FDA's interim acceptable exposure limit of 9.82 ppm. Based on available information, the risk of developing cancer in patients following long-term use of the drug cannot be ruled out. The affected products of the recall are detailed on Table 1.

Table 1. Affected products of Losartan

NDC	Product	Count	Affected Lot	Expiration Date
60429-318-90	Losartan Potassium Tablets USP 100 mg	90	GS014045	Jun 2019
60429-318-90	Losartan Potassium Tablets USP 100 mg	90	GS014305	Jun 2019
60429-318-10	Losartan Potassium Tablets USP 100 mg	1,000	GS014054	Jun 2019
60429-318-90	Losartan Potassium Tablets USP 100 mg	90	GS014044	Jun 2019
60429-316-10	Losartan Potassium Tablets USP 25 mg	1,000	GS014817	Jun 2019
60429-316-90	Losartan Potassium Tablets USP 25 mg	90	GS015172	Jun 2019
60429-316-10	Losartan Potassium Tablets USP 25 mg	1,000	GS015204	Jun 2019
60429-318-10	Losartan Potassium Tablets USP 100 mg	1,000	GS016338	Dec 2019
60429-318-10	Losartan Potassium Tablets USP 100 mg	1,000	GS016341	Jan 2020
60429-318-10	Losartan Potassium Tablets USP 100 mg	1,000	GS016342	Jan 2020
60429-318-10	Losartan Potassium Tablets USP 100 mg	1,000	GS016343	Jan 2020
60429-318-10	Losartan Potassium Tablets USP 100 mg	1,000	GS016344	Jan 2020
60429-318-10	Losartan Potassium Tablets USP 100 mg	1,000	GS016345	Jan 2020
60429-318-90	Losartan Potassium Tablets USP 100 mg	90	GS016535	Jan 2020

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Table 1. Affected products of Losartan

NDC	Product	Count	Affected Lot	Expiration Date
60429-318-90	Losartan Potassium Tablets USP 100 mg	90	GS016524	Jan 2020
60429-318-10	Losartan Potassium Tablets USP 100 mg	1,000	GS016539	Jan 2020
60429-318-10	Losartan Potassium Tablets USP 100 mg	1,000	GS016969	Jan 2020
60429-318-10	Losartan Potassium Tablets USP 100 mg	1,000	GS016973	Jan 2020
60429-318-10	Losartan Potassium Tablets USP 100 mg	1,000	GS017337	Jan 2020
60429-318-90	Losartan Potassium Tablets USP 100 mg	90	GS017384	Feb 2020
60429-318-90	Losartan Potassium Tablets USP 100 mg	90	GS017385	Jan 2020
60429-318-90	Losartan Potassium Tablets USP 100 mg	90	GS017539	Jan 2020
60429-318-90	Losartan Potassium Tablets USP 100 mg	90	GS017540	Jan 2020
60429-318-90	Losartan Potassium Tablets USP 100 mg	90	GS017543	Jan 2020
60429-318-90	Losartan Potassium Tablets USP 100 mg	90	GS017542	Jan 2020
60429-318-10	Losartan Potassium Tablets USP 100 mg	1,000	GS018524	Feb 2020
60429-318-90	Losartan Potassium Tablets USP 100 mg	90	GS017984	Feb 2020
60429-318-90	Losartan Potassium Tablets USP 100 mg	90	GS017985	Feb 2020
60429-318-90	Losartan Potassium Tablets USP 100 mg	90	GS017986	Feb 2020
60429-318-90	Losartan Potassium Tablets USP 100 mg	90	GS018263	Feb 2020
60429-318-90	Losartan Potassium Tablets USP 100 mg	90	GS018264	Feb 2020
60429-316-90	Losartan Potassium Tablets USP 25 mg	90	GS017634	Feb 2020
60429-316-90	Losartan Potassium Tablets USP 25 mg	90	GS017653	Feb 2020
60429-316-90	Losartan Potassium Tablets USP 25 mg	90	GS017980	Feb 2020
60429-316-30	Losartan Potassium Tablets USP 25 mg	30	GS017981	Feb 2020
60429-318-90	Losartan Potassium Tablets USP 100 mg	90	GS018265	Feb 2020
60429-316-90	Losartan Potassium Tablets USP 25 mg	90	GS016726	Feb 2020
60429-316-30	Losartan Potassium Tablets USP 25 mg	30	GS016958	Feb 2020
60429-316-90	Losartan Potassium Tablets USP 25 mg	90	GS017045	Feb 2020
60429-316-90	Losartan Potassium Tablets USP 25 mg	90	GS017276	Feb 2020
60429-316-30	Losartan Potassium Tablets USP 25 mg	30	GS017341	Feb 2020
60429-316-10	Losartan Potassium Tablets USP 25 mg	1,000	GS018318	Feb 2020
60429-316-10	Losartan Potassium Tablets USP 25 mg	1,000	GS017342	Feb 2020
60429-316-10	Losartan Potassium Tablets USP 25 mg	1,000	GS017808	Feb 2020

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. For questions, contact Teva Medical Information by phone at: 888-838-2872, option 3, then, option 4. Live calls are received Monday-Friday, 9:00AM-5:00PM Eastern Time with voicemail available 24 hours/day, 7 days/week or by email at druginfo@tevapharm.com.

For additional information visit:

https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/teva-pharmaceuticals-usa-inc-issues-voluntary-nationwide-recall-losartan-potassium-25-mg-and-100-mg?utm_campaign=FDA%20MedWatch%20Losartan%20Potassium%2025%20mg%20and%20100%20mg%20Tablets%20by%20Teva%20Pharmaceuticals&utm_medium=email&utm_source=Eloqua

Department of Clinical Pharmacy

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