March 1, 2019

COM-2019-011

Recall: Voluntary Recall of Losartan Potassium and Losartan/Hydrochlorothiazide Tablets

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 February 22, 2019 the US Food and Drug Administration (FDA) issued a statement notifying that Macleods Pharmaceuticals Limited is voluntarily recalling one lot of Losartan Potassium/Hydrochlorothiazide combination tablets. The recall was made because this lot does not meet safety standards due to the presence of the impurity N-nitrosodiethylamine (NDEA), a substance that could cause cancer. The product affected by the recall is detailed on Table 1.

Likewise, the FDA published a statement on February 28, 2019 mentioning that Camber Pharmaceuticals, Inc. is recalling 87 lots of Losartan tablets, USP. The recall was prompted due to the detection of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) a possible impurity, which is also a potential human carcinogen. The products affected by the recall are detailed on Table 2.

Table 1. Affected product of Losartan Potassium / Hydrochlorothiazide

NDC	Product	Count	Affected Lot	Expiration Date
33342-0052-10	Losartan Potassium / Hydrochlorothiazide combination tablets 100mg/25mg	90	BLM715A	Jul -2019

Table 2. Affected products of Losartan

NDC	Product	Count	Affected Lot	Expiration Date
31722-700-90	Losartan Potassium Tablets USP 25 mg	90	LOP17026B	Sep-19
31722-700-90	Losartan Potassium Tablets USP 25 mg	90	LOP17050	Sep-19
31722-700-90	Losartan Potassium Tablets USP 25 mg	90	LOP17051	Sep-19
31722-700-90	Losartan Potassium Tablets USP 25 mg	90	LOP17052	Sep-19
31722-700-90	Losartan Potassium Tablets USP 25 mg	90	LOP17053	Sep-19
31722-700-90	Losartan Potassium Tablets USP 25 mg	90	LOP17061	Oct-19
31722-700-90	Losartan Potassium Tablets USP 25 mg	90	LOP18035	Dec-19
31722-700-90	Losartan Potassium Tablets USP 25 mg	90	LOP18036	Dec-19
31722-700-05	Losartan Potassium Tablets USP 25 mg	500	LOP17026	Sep-19
31722-700-10	Losartan Potassium Tablets USP 25 mg	1000	LOP17006	May-19
31722-700-10	Losartan Potassium Tablets USP 25 mg	1000	LOP17025	Sep-19
31722-700-10	Losartan Potassium Tablets USP 25 mg	1000	LOP17068	Oct-19
31722-700-10	Losartan Potassium Tablets USP 25 mg	1000	LOP18037	Dec-19
31722-700-10	Losartan Potassium Tablets USP 25 mg	1000	LOP18038	Dec-19
31722-700-10	Losartan Potassium Tablets USP 25 mg	1000	LOP18039	Dec-19
31722-700-10	Losartan Potassium Tablets USP 25 mg	1000	LOP18057	Jan-20
31722-701-30	Losartan Potassium Tablets USP 50 mg	30	LOP17028C	Sep-19

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Table 2. Affected products of Losartan

31722-701-30	Losartan Potassium Tablets USP 50 mg	30	LOP17064A	Nov-19
31722-701-90	Losartan Potassium Tablets USP 50 mg	90	LOP17027	Sep-19
31722-701-90	Losartan Potassium Tablets USP 50 mg	90	LOP17063	Nov-19
31722-701-90	Losartan Potassium Tablets USP 50 mg	90	LOP17093	Nov-19
31722-701-90	Losartan Potassium Tablets USP 50 mg	90	LOP17094	Dec-19
31722-701-90	Losartan Potassium Tablets USP 50 mg	90	LOP17095	Dec-19
31722-701-90	Losartan Potassium Tablets USP 50 mg	90	LOP17097A	Dec-19
31722-701-90	Losartan Potassium Tablets USP 50 mg	90	LOP17105	Dec-19
31722-701-90	Losartan Potassium Tablets USP 50 mg	90	LOP17107	Dec-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP17004	Dec-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP17028B	Sep-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP17048	Oct-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP17049	Oct-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP17056	Nov-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP17073	Nov-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP17074	Nov-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP17076	Nov-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP17096	Dec-19
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP18077A	Feb-20
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP18078	Feb-20
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP18079	Feb-20
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP18080	Feb-20
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP18081	Mar-20
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP18084	Mar-20
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP18095	Mar-20
31722-701-10	Losartan Potassium Tablets USP 50 mg	1000	LOP18096	Mar-20
31722-702-30	Losartan Potassium Tablets USP 100 mg	30	LOP17011	Aug-19
31722-702-30	Losartan Potassium Tablets USP 100 mg	30	LOP17087	Nov-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP17012	Aug-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP17013	Aug-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP17042	Oct-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP17043	Oct-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP17044	Nov-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP17045	Nov-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP18024	Dec-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP18025	Dec-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP18026	Dec-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP18027	Dec-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP18028	Dec-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP18029	Dec-19
31722-702-90	Losartan Potassium Tablets USP 100 mg	90	LOP18030	Dec-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP17005	May-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP17014	Aug-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP17016	Sep-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP17023	Sep-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP17083	Oct-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP17084	Nov-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP17085	Nov-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP17086	Nov-19

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Table 2. Affected products of Losartan

31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18021	Dec-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18022	Dec-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18023	Dec-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18031	Dec-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18032	Dec-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18033	Dec-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18050	Dec-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18051	Dec-19
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18109	Mar-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18111	Mar-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18122	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18123	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18124	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18125	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18126	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18127	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18128	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18129	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18130	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18131C	Jun-20
31722-702-10	Losartan Potassium Tablets USP 100 mg	1000	LOP18133	Jun-20

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 Camber Pharmaceuticals' Med Line at 1-866-495-1995 Monday – Friday, 9am – 5pm
4. Contact Qualanex via email at recall@qualanex.com or call 888-280-2042 (7:00 am to 4:00 pm CST Monday to Friday regarding the return of this product. EST.

For additional information visit:

https://www.fda.gov/Safety/Recalls/ucm631880.htm

https://www.fda.gov/Safety/Recalls/ucm632395.htm

Department of Clinical Pharmacy

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