



## Drug Recall

**DATE OF RECALL:** March 01, 2019

**DRUG NAME:** Losartan Potassium

**RECALLING FIRM:** Camber Pharmaceuticals, Inc

**REASON FOR RECALL:** This recall was issued due to the detection of trace amounts of N-Nitroso N-Methyl 4-amino butyric acid (NMBA) a possible process impurity or contaminant in an active pharmaceutical ingredient, manufactured by Hetero Labs Limited, Unit – I (API manufacturer).

**FDA LINK:** <https://www.fda.gov/Safety/Recalls/ucm632395.htm>

**OTHER DETAILS:** See FDA link.

### RECALLED PRODUCT:

Product Description	NDC Number	Affected Lots	Expiration Date
Losartan Potassium Tablets USP 25 mg, 90 count bottle	31722-0700-90	LOP17026B	Sep-19
		LOP17050	Sep-19
		LOP17051	Sep-19
		LOP17052	Sep-19
		LOP17053	Sep-19
		LOP17061	Oct-19
		LOP18035	Dec-19
		LOP18036	Dec-19
Losartan Potassium Tablets USP 25 mg, 500 count bottle	31722-0700-05	LOP17026	Sep-19
Losartan Potassium Tablets USP 25 mg, 1000 count bottle	31722-0700-10	LOP17006	May-19
		LOP17025	Sep-19
		LOP17068	Oct-19
		LOP18037	Dec-19
		LOP18038	Dec-19
		LOP18039	Dec-19
		LOP18057	Jan-20
Losartan Potassium Tablets USP 50 mg, 30 count bottle	31722-0701-30	LOP17028C	Sep-19
		LOP17064A	Nov-19
*Losartan Potassium Tablets USP 50 mg, 90 count bottle	31722-0701-90	LOP17027 LOP17063	Sep-19 Nov-19



		LOP17093 LOP17094 LOP17095 LOP17097A LOP17105 LOP17107	Nov-19 Dec-19 Dec-19 Dec-19 Dec-19 Dec-19
Losartan Potassium Tablets USP 50 mg, 1000 count bottle	31722-0701-10	LOP17004 LOP17028B LOP17048 LOP17049 LOP17056 LOP17073 LOP17074 LOP17076 LOP17096 LOP18077A LOP18078 LOP18079 LOP18080 LOP18081 LOP18084 LOP18095 LOP18096	Dec-19 Sep-19 Oct-19 Oct-19 Nov-19 Nov-19 Nov-19 Nov-19 Dec-19 Feb-20 Feb-20 Feb-20 Feb-20 Mar-20 Mar-20 Mar-20 Mar-20
Losartan Potassium Tablets USP 100 mg, 30 count bottle	31722-0702-30	LOP17011 LOP17087	Aug-19 Nov-19
Losartan Potassium Tablets USP 100 mg, 90 count bottle	31722-0702-90	LOP17012 LOP17013 LOP17042 LOP17043 LOP17044 LOP17045 LOP18024 LOP18025 LOP18026 LOP18027 LOP18028 LOP18029 LOP18030	Aug-19 Aug-19 Oct-19 Oct-19 Nov-19 Nov-19 Dec-19 Dec-19 Dec-19 Dec-19 Dec-19 Dec-19 Dec-19
Losartan Potassium Tablets USP 100 mg, 10000 count bottle	31722-0702-10	LOP17005 LOP17014 LOP17016 LOP17023 LOP17083 LOP17084 LOP17085 LOP17086	May-19 Aug-19 Sep-19 Sep-19 Oct-19 Nov-19 Nov-19 Nov-19



		LOP18021	Dec-19
		LOP18022	Dec-19
		LOP18023	Dec-19
		LOP18031	Dec-19
		LOP18032	Dec-19
		LOP18033	Dec-19
		LOP18050	Dec-19
		LOP18051	Dec-19
		LOP18109	Mar-20
		LOP18111	Mar-20
		LOP18122	Jun-20
		LOP18123	Jun-20
		LOP18124	Jun-20
		LOP18125	Jun-20
		LOP18126	Jun-20
		LOP18127	Jun-20
		LOP18128	Jun-20
		LOP18129	Jun-20
		LOP18130	Jun-20
		LOP18131C	Jun-20
		LOP18133	Jun-20