

## Recall of Losartan by Camber Effective Date: February 28, 2019

On February 28, 2019, Camber announced a voluntary recall of several lots of Losartan tablets because of the presence of trace amounts of an unexpected impurity, n-nitroso n-methyl 4-amino butyric acid (NMBA) a possible process impurity or contaminant in an active pharmaceutical ingredient, manufactured by Hetero Labs. NMBA is a probable human carcinogen.

It is possible that you already received a letter regarding an angiotensin receptor blocker (ARB) recall. The FDA continues to monitor this situation and investigates additional ARB products which may be impacted by the impurity issue. We continue to notify any potentially impacted members as the FDA announces the recall of additional ARB products.

OptumRx notifies members who may be affected by this recall. These members were advised to contact their pharmacy for replacement information, provided information to help them identify if their medication is being recalled, advised to discuss potential alternative therapies with their healthcare provider if they are not able to obtain a replacement, and advised to continue their current therapy until they obtain a replacement. In the future, these members may inquire about the Losartan prescription(s) your pharmacy dispensed.

If you have any questions, call Camber at **866-495-1995** (9:00 AM - 5:00 PM EST, Monday through Friday) for more information.

## **Losartan Tablets Recalled by Camber**

Product Description	NDC #	Lot # (Expiration Date)					
Losartan Tablets 25 mg	31722-0700-90	LOP17026B (9/2019); LOP17050 (9/2019); LOP17051 (9/2019); LOP17052 (9/2019); LOP17053 (9/2019); LOP17061 (10/2019); LOP18035 (12/2019); LOP18036 (12/2019)					
	31722-0700-05	LOP17026 (9/2019)					
	31722-0700-10	LOP17006 (5/2019); LOP17025 (9/2019); LOP17068 (10/2019); LOP18037 (12/2019); LOP18038 (12/2019); LOP18039 (12/2019); LOP18057 (1/2020)					
Losartan Tablets 50 mg	31722-0701-30	LOP17028C (9/2019); LOP17064A (11/2019)					
	31722-0701-90	LOP17027 (9/2019); LOP17063 (11/2019); LOP17093 (11/2019); LOP17094 (12/2019); LOP17095 (12/2019); LOP17097A (12/2019); LOP17105 (12/2019); LOP17107 (12/2019)					
	31722-0701-10	LOP17004 (12/2019); LOP17028B (9/2019); LOP17048 (10/2019); LOP17049 (10/2019); LOP17056 (11/2019); LOP17073 (11/2019); LOP17074 (11/2019); LOP17076 (11/2019); LOP17096 (12/2019); LOP18077A (2/2020); LOP18078 (2/2020); LOP18079 (2/2020); LOP18080 (2/2020); LOP18081 (3/2020); LOP18084 (3/2020); LOP18095 (3/2020); LOP18096 (3/2020)					
Losartan Tablets 100 mg	31722-0702-30	LOP17011 (8/2019); LOP17087 (11/2019)					
	31722-0702-90	LOP17012 (8/2019); LOP17013 (8/2019); LOP17042 (10/2019); LOP17043 (10/2019); LOP17044 (11/2019); LOP17045 (11/2019); LOP18024 (12/2019); LOP18025 (12/2019); LOP18026 (12/2019); LOP18027 (12/2019); LOP18028 (12/2019); LOP18029 (12/2019); LOP18030 (12/2019)					
	31722-0702-10	LOP17005 (5/2019);LOP17014 (8/2019); LOP17016 (9/2019); LOP17023 (9/2019); LOP17083 (10/2019); LOP17084(11/2019); LOP17085 (11/2019); LOP17086 (11/2019);LOP18021 (12/2019); LOP18022 (12/2019); LOP18023 (12/2019); LOP18031 (12/2019); LOP18032 (12/2019); LOP18033 (12/2019); LOP18051 (12/2019); LOP18051 (12/2019); LOP18051 (12/2019); LOP18109 (3/2020); LOP18111 (3/2020);					

Please distribute immediately.

For questions regarding communications, contact the Pharmacy Provider Communications team: pharmacyprovidercommunications@optum.com



LOP18122 (6/2020); LOP18123 (6/2020); LOP18124 (6/2020); LOP18125 (6/2020); LOP18126 (6/2020); LOP18127 (6/2020); LOP18128 (6/2020); LOP18129 (6/2020); LOP18130 (6/2020);
LOP18131C (6/2020); LOP18133 (6/2020); LOP18131C (6/2020); LOP18133 (6/2020)

Due to the large scale and ongoing nature of ARB recalls, certain ARB products, such as Losartan, may be in limited supply for the near-term. Please refer to the table below for potential alternative ARB therapies. All ARBs are available generically with the exception of Edarbi.

FDA-approved indications for single-entity Angiotensin Receptor Blockers (ARBs)

Indication	Atacand (Candesartan)	Avapro (Irbesartan)	Benicar (Olmesartan)	Cozaar (Losartan)	Diovan (Valsartan)	Edarbi (Azilsartan)	Eprosartan	Micardis (Telmisartan)
Hypertension in adults		>	>	>	>	~	<b>&gt;</b>	<b>&gt;</b>
Hypertension in children ages 1 to < 17 years								
Hypertension in children ages 6 to 16 years			>	>	>			
Treatment of diabetic nephropathy in hypertensive patients with type 2 DM, an elevated serum creatinine, and proteinuria		>		<b>&gt;</b>				
Heart failure (NYHA Class II to IV) in adults					>			
Reduction in the risk of stroke in patients with hypertension and LV hypertrophy				>				
Post-MI: Reduction of cardiovascular mortality in clinically stable patients with LV failure or LV dysfunction					>			
Cardiovascular risk reduction in patients 55 years of age or older at high risk of developing major cardiovascular events who are unable to take ACE-Is								•

**Abbreviations**: ACE-I = Angiotensin Converting Enzyme Inhibitor; LV = Left Ventricular; MI = Myocardial Infarction; NYHA = New York Heart Association