

IMPORTANT INFORMATION REGARDING

Recall of generic valsartan and valsartan-HCTZ by
Solco Healthcare, Major and Teva

On July 13, 2018, the FDA announced a voluntary recall of the generic angiotensin receptor blocker (ARB) valsartan and valsartan-HCTZ tablets manufactured by Solco, Major, and Teva, because of the presence of an impurity, N-nitrosodimethylamine (NDMA). NDMA is classified as a probable human carcinogen. The presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured. At this point, the recall is limited to these three manufacturers due their specific supply sourcing of raw materials.

Due to the large scale nature of this recall, valsartan and valsartan-HCTZ products may be in limited supply for the near-term. Please refer to the tables in the following pages for potential alternative ARB therapies and equivalent daily dosing to valsartan.

OptumRx is notifying members who may be affected by this recall. These members were advised to contact their pharmacy for potential replacement with an alternative valsartan product from a different manufacturer (pending availability). We also provided information on potential alternative ARB therapies to discuss with you if they are not able to obtain a replacement, and advised to continue their current therapy per FDA guidance until they obtain such replacement.

Should you have any questions or require assistance, please contact:

Major: (800) 616-2471 (8:00 a.m. - 8:00 p.m. EST, Monday through Friday)

Solco Healthcare: (866) 931-9829 (9:00 a.m. - 5:00 p.m. EST, Monday through Friday)

Teva: (888) 838-2872 (9:00 a.m. - 5:00 p.m. EST, Monday through Friday)

For questions regarding this communication or other pharmacy related claims processing issues:
Call Provider Relations (877) 633-4701 OR E-mail provider.relations@optum.com

Please distribute immediately.