

July 17,2018

COM-2018-014

Dear provider of pharmaceutical services,

Receive kind greetings from Pharmpix,

Recall: Voluntary recall of several medicines containing valsartan

At PharmPix we are committed to the health and well-being of patients. It is for this reason that we inform that on July 13, 2018 the US Food and Drug Administration (FDA) issued a statement notifying the retirement of several drugs containing the active ingredient valsartan. The recall was made due to the presence of the impurity, N-nitrosodimethylamine (NDMA), a substance that could cause cancer. These drugs, does not meet the safety standards. However, not all products containing valsartan are being recalled. The valsartan products affected are detailed on Table 1.

Table 1. Affected products of Valsartan

Product	Affected Lot	Company
Valsartan	All	Major Pharmaceuticals
Valsartan	All	Solco Healthcare
Valsartan	All	Teva Pharmaceuticals Industries Ltd.
Valsartan/hydrochlorothiazide (HCTZ)	All	Solco Healthcare
Valsartan/hydrochlorothiazide (HCTZ)	All	Teva Pharmaceuticals Industries Ltd.

The Pharmacy must:

1. Identify if they have the product in inventory and immediately stop using and dispensing the product.
2. It is important that pharmacy 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 regarding this recall please visit FDA website.

For additional information please visit:

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm>

In addition, if you have any doubt or wish to have more information regarding this document, you can call us to 787-522-5252.

Regards,

Department of Clinical Pharmacy