November 21, 2018

COM – 2018 - 023

Recall: Voluntary recall of several medicines containing valsartan, amlodipine and valsartan, and valsartan and hydrochlorothiazide

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 November 20, 2018 the US Food and Drug Administration (FDA) issued a statement notifying the retirement of several drugs containing the following active ingredients: valsartan, amlodipine and valsartan, and valsartan and hydrochlorothiazide. The products were manufactured by Mylan Laboratories and Mylan Pharmaceuticals. The recall was made because these drugs does not meet safety standards due to the presence of the impurity N-nitrosodimethylamine (NDMA), a substance that could cause cancer. However, not all products containing valsartan, amlodipine and valsartan, and valsartan and hydrochlorothiazide are being recalled. The products affected are detailed on Table 1.

Table 1. Affected products

Product	Affected Lot	Expiration date	NDC
Amlodipine and Valsartan Tablets, USP 5mg/160mg, 30 ct	3066051	03/2018	00378-1721-93
Amlodipine and Valsartan Tablets, USP 10mg/160mg, 30 ct	3079500	01/2020	00378-1722-93
Amlodipine and Valsartan Tablets, USP 10mg/320mg, 30 ct	3061986	11/2018	00378-1724-93
Amlodipine and Valsartan Tablets, USP 10mg/320mg, 30 ct	3079709	01/2020	00378-1724-93
Amlodipine and Valsartan Tablets, USP 10mg/320mg, 30 ct	3077618	11/2019	00378-1724-93
Amlodipine and Valsartan Tablets, USP 10mg/320mg, 30 ct	3079708	01/2020	00378-1724-93
Valsartan Tablets, USP 80mg, 90ct	3063782	01/2019	00378-5813-77
Valsartan Tablets, USP 160mg, 90ct	3071352	07/2019	00378-5814-77
Valsartan Tablets, USP 40mg, 30ct	3061169	11/2018	00378-5807-93

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Table 1. Affected products

Product	Affected Lot	Expiration date	NDC
Valsartan Tablets, USP 320mg, 90ct	3081499	03/2020	00378-5815-77
Valsartan Tablets, USP 320mg, 90ct	3080009	02/2020	00378-5815-77
Valsartan Tablets, USP 320mg, 90ct	3080010	02/2020	00378-5815-77
Valsartan Tablets, USP 320mg, 90ct	3079205	01/2020	00378-5815-77
Valsartan and Hydrochlorothiazide Tablets, USP 320mg/25mg, 500ct	3084886	02/2019	00378-6325-05
Valsartan and Hydrochlorothiazide Tablets, USP 320mg/25mg, 500ct	3093804	12/2019	00378-6325-05

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 Stericycle at 1-888-406-9305 for questions regarding the recalled product and return of the recalled product. Normal business hours are Monday through Friday 8:00am to 5:00pm EST.

For additional information visit:

https://www.fda.gov/Safety/Recalls/ucm626367.htm

Department of Clinical Pharmacy

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