November 28, 2018

COM-2018-025

Recall: Teva Pharmaceuticals USA issues voluntary recall of all valsartan/amlodipine and valsartan/amlodipine/hydrochlorothiazide combination tablets that are within expiry

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 27, 2018 the US Food and Drug Administration (FDA) issued a statement notifying the retirement of all drugs containing the following combination of active ingredients: valsartan/ amlodipine and valsartan/amlodipine/hydrochlorothiazide. The products were manufactured by Teva Pharmaceutical. The recall was made because these drugs does not meet safety standards due to the presence of the impurity N-nitrosodiethylamine (NDEA), a substance that could cause cancer. The products affected are detailed on Table 1.

Table 1. Affected products

Product	Affected Lot	Expiration date	NDC
Amlodipine and Valsartan Tablets 5 mg/160 mg, 90 ct	23X017	11/2018	0093-7690-98
Amlodipine and Valsartan Tablets 5 mg/160 mg, 30 ct	23X018	11/2018	0093-7690-56
Amlodipine and Valsartan Tablets 5 mg/160 mg, 90 ct	23X018	11/2018	0093-7690-98
Amlodipine and Valsartan Tablets 5 mg/160 mg, 30 ct	23X019	11/2018	0093-7690-56
Amlodipine and Valsartan Tablets 5 mg/160 mg, 90 ct	23X019	11/2018	0093-7690-98
Amlodipine and Valsartan Tablets 5 mg/160 mg, 30 ct	23X020	11/2018	0093-7690-56
Amlodipine and Valsartan Tablets 5 mg/160 mg, 30ct	23X022	04/2019	0093-7690-56
Amlodipine and Valsartan Tablets 5 mg/160 mg, 30ct	23X023	04/2019	0093-7690-56
Amlodipine and Valsartan Tablets 5 mg/160 mg, 90ct	23X023	4/2019	0093-7690-98
Amlodipine and Valsartan Tablets 5 mg/160 mg, 90ct	23X024	4/2019	0093-7690-98
Amlodipine and Valsartan Tablets 10 mg/160 mg, 30ct	24X012	11/2018	0093-7691-56
Amlodipine and Valsartan Tablets 10 mg/160 mg, 90ct	24X012	11/2018	0093-7691-98

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Table 1. Affected products

Product	Affected Lot	Expiration date	NDC
Amlodipine and Valsartan Tablets 10 mg/160 mg, 30ct	24X013	11/2018	0093-7691-56
Amlodipine and Valsartan Tablets 5 mg/320 mg, 90ct	25X028	11/2018	0093-7692-98
Amlodipine and Valsartan Tablets 5 mg/320 mg, 30ct	25X029	11/2018	0093-7692-56
Amlodipine and Valsartan Tablets 5 mg/320 mg, 90ct	25X029	11/2018	0093-7692-98
Amlodipine and Valsartan Tablets 5 mg/320 mg, 30ct	25X030	11/2018	0093-7692-56
Amlodipine and Valsartan Tablets 5 mg/320 mg, 30ct	25X031	11/2018	0093-7692-56
Amlodipine and Valsartan Tablets 5 mg/320 mg, 30ct	25X032	11/2018	0093-7692-56
Amlodipine and Valsartan Tablets 5 mg/320 mg, 30ct	25X035	4/2019	0093-7692-56
Amlodipine and Valsartan Tablets 5 mg/320 mg, 30ct	25X037	4/2019	0093-7692-56
Amlodipine and Valsartan Tablets 10 mg/320 mg, 90ct	26X036	11/2018	0093-7693-98
Amlodipine and Valsartan Tablets 10 mg/320 mg, 90ct	26X038	11/2018	0093-7693-98
Amlodipine and Valsartan Tablets, 30ct	26X039	11/2018	0093-7693-56
Amlodipine and Valsartan Tablets 10 mg/320 mg, 90ct	26X039	11/2018	0093-7693-98
Amlodipine and Valsartan Tablets 10 mg/320 mg, 30ct	26X040	11/2018	0093-7693-56
Amlodipine and Valsartan Tablets 10 mg/320 mg, 30ct	26X041	11/2018	0093-7693-56
Amlodipine and Valsartan Tablets 10 mg/320 mg, 30ct	26X042	11/2018	0093-7693-56
Amlodipine and Valsartan Tablets 10 mg/320 mg, 30ct	26X043	11/2018	0093-7693-56
Amlodipine and Valsartan Tablets 10 mg/320 mg, 90ct	26X044	4/2019	0093-7693-98
Amlodipine and Valsartan Tablets 10 mg/320 mg, 90ct	26X045	4/2019	0093-7693-98
Amlodipine and Valsartan Tablets 10 mg/320 mg, 30ct	26X046	4/2019	0093-7693-56
Amlodipine and Valsartan Tablets 10 mg/320 mg, 30ct	26X047	4/2019	0093-7693-56
Amlodipine and Valsartan Tablets 10 mg/320 mg, 30ct	26X048	4/2019	0093-7693-56
Amlodipine and Valsartan Tablets 10 mg/320 mg, 30ct	26X049	4/2019	0093-7693-56
Amlodipine and Valsartan Tablets 10 mg/320 mg, 30ct	26X050	4/2019	0093-7693-56
Amlodipine and Valsartan Tablets 10 mg/320 mg, 30ct	26X051	04/2019	0093-7693-56

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Table 1. Affected products

Product	Affected Lot	Expiration date	NDC
Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 5 mg/160 mg/12.5 mg, 30ct	18X010	02/2019	0093-7807-56
Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 5 mg/160 mg/12.5 mg, 90ct	18X010	02/2019	0093-7807-98
Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 5 mg/160 mg/12.5 mg, 30ct	18X011	02/2019	0093-7807-56
Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 5 mg/160 mg/12.5 mg, 30ct	20X006	11/2018	0093-7810-56
Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 5 mg/160 mg/12.5 mg, 90ct	20X006	11/2018	0093-7810-98
Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 10 mg/160 mg/25 mg, 30ct	21X006	11/2018	0093-7038-56
Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 10 mg/160 mg/25 mg, 90ct	21X006	11/2018	0093-7038-98
Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 10 mg/160 mg/25 mg, 30ct	21X007	02/2019	0093-7038-56
Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 10 mg/320 mg/25 mg, 30ct	22X045	02/2019	0093-7809-56
Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 10 mg/320 mg/25 mg, 90ct	22X045	02/2019	0093-7809-98
Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 10 mg/320 mg/25 mg, 30ct	22X046	02/2019	0093-7809-56
Amlodipine, Valsartan, and Hydrochlorothiazide Tablets 10 mg/320 mg/25 mg, 30ct	22X047	02/2019	0093-7809-56

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 Teva's Medical Information by phone at: 888-838-2872, option 3, then, option 4 for questions regarding the recalled product. Normal business hours are Monday through Friday 9:00am to 5:00pm EST.

For additional information visit:

https://www.fda.gov/Safety/Recalls/ucm626802.htm

Department of Clinical Pharmacy

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