December 5, 2018

COM-2018-027

Recall: Voluntary recall of medicines containing valsartan, amlodipine and valsartan, and valsartan and hydrochlorothiazide has been expanded

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 December 4, 2018 the US Food and Drug Administration (FDA) issued a statement notifying that Mylan Pharmaceuticals has expanded its voluntary recall of valsartan, valsartan/amlodipine, and valsartan/hydrochlorothiazide to all lots of valsartan-containing products with in expiry. The recall was made because these drugs does not meet safety standards due to the presence of trace amounts of the impurity N-nitrosodiethylamine (NDEA), a substance that could cause cancer. The products affected by this expanded recall are detailed on Table 1.

Table 1. Affected products

Product	Affected Lot	Expiration date	NDC
Amlodipine and Valsartan Tablets 5 mg/160 mg, 30 ct	3064084	1/2019	0378-1721-93
Amlodipine and Valsartan Tablets 5 mg/160 mg, 30 ct	3069629	5/2019	0378-1721-93
Amlodipine and Valsartan Tablets 5 mg/160 mg, 30 ct	3073148	8/2019	0378-1721-93
Amlodipine and Valsartan Tablets 5 mg/160 mg, 30 ct	3073149	8/2019	0378-1721-93
Amlodipine and Valsartan Tablets 5 mg/160 mg, 30 ct	3076093	10/2019	0378-1721-93
Amlodipine and Valsartan Tablets 5 mg/160 mg, 30 ct	3077772	11/2019	0378-1721-93
Amlodipine and Valsartan Tablets 10 mg/160 mg, 30ct	3064085	01/2019	0378-1722-93
Amlodipine and Valsartan Tablets 10 mg/160 mg, 30ct	3066063	03/2019	0378-1722-93
Amlodipine and Valsartan Tablets 10 mg/160 mg, 30ct	3069638	05/2019	0378-1722-93
Amlodipine and Valsartan Tablets 10 mg/160 mg, 30ct	3069639	06/2019	0378-1722-93
Amlodipine and Valsartan Tablets 5 mg/320 mg, 30ct	3064086	01/2019	0378-1723-93
Amlodipine and Valsartan Tablets 5 mg/320 mg, 30ct	3066061	03/2019	0378-1723-93
Amlodipine and Valsartan Tablets 5 mg/320 mg, 30ct	3066062	03/2019	0378-1723-93

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Table 1. Affected products

Product	Affected Lot	Expiration date	NDC
Amlodipine and Valsartan Tablets 5 mg/320 mg, 30ct	3073145	09/2019	0378-1723-93
Amlodipine and Valsartan Tablets 5 mg/320 mg, 30ct	3073146	09/2019	0378-1723-93
Amlodipine and Valsartan Tablets 5 mg/320 mg, 30ct	3073147	09/2019	0378-1723-93
Amlodipine and Valsartan Tablets 5 mg/320 mg, 30ct	3076091	11/2019	0378-1723-93
Amlodipine and Valsartan Tablets 5 mg/320 mg, 30ct	3077619	11/2019	0378-1723-93
Amlodipine and Valsartan Tablets 5 mg/320 mg, 30ct	3082432	03/2020	0378-1723-93
Amlodipine and Valsartan Tablets 10 mg/320 mg, 30ct	3066064	03/2019	0378-1724-93
Amlodipine and Valsartan Tablets 10 mg/320 mg, 30ct	3069645	06/2019	0378-1724-93
Amlodipine and Valsartan Tablets 10 mg/320 mg, 30ct	3069646	06/2019	0378-1724-93
Amlodipine and Valsartan Tablets 10 mg/320 mg, 30ct	3073142	09/2019	0378-1724-93
Amlodipine and Valsartan Tablets 10 mg/320 mg, 30ct	3073143	09/2019	0378-1724-93
Amlodipine and Valsartan Tablets 10 mg/320 mg, 30ct	3073144	09/2019	0378-1724-93
Amlodipine and Valsartan Tablets 10 mg/320 mg, 30ct	3077617	11/2019	0378-1724-93
Valsartan Tablets, USP 40 mg, 30ct	3063780	01/2019	0378-5807-93
Valsartan Tablets, USP 40 mg, 30ct	3074879	10/2019	0378-5807-93
Valsartan Tablets, USP 40 mg, 30ct	3086684	06/2020	0378-5807-93
Valsartan Tablets, USP 40 mg, 30ct	3086687	06/2020	0378-5807-93
Valsartan Tablets, USP 80 mg, 90ct	3065445	02/2019	0378-5813-77
Valsartan Tablets, USP 80 mg, 90ct	3074880	10/2019	0378-5813-77
Valsartan Tablets, USP 80 mg, 90ct	3074883	10/2019	0378-5813-77
Valsartan Tablets, USP 80 mg, 90ct	3086688	06/2020	0378-5813-77
Valsartan Tablets, USP 80 mg, 90ct	3086689	06/2020	0378-5813-77
Valsartan Tablets, USP 80 mg, 90ct	3086710	06/2020	0378-5813-77
Valsartan Tablets, USP 160 mg, 90ct	3069019	05/2019	0378-5814-77
Valsartan Tablets, USP 160 mg, 90ct	3069020	05/2019	0378-5814-77
Valsartan Tablets, USP 160 mg, 90ct	3069021	05/2019	0378-5814-77
Valsartan Tablets, USP 160 mg, 90ct	3069022	05/2019	0378-5814-77
Valsartan Tablets, USP 160 mg, 90ct	3071354	07/2019	0378-5814-77
Valsartan Tablets, USP 160 mg, 90ct	3071355	07/2019	0378-5814-77
Valsartan Tablets, USP 160 mg, 90ct	3071357	07/2019	0378-5814-77
Valsartan Tablets, USP 160 mg, 90ct	3079023	01/2020	0378-5814-77
Valsartan Tablets, USP 160 mg, 90ct	3079027	01/2020	0378-5814-77
Valsartan Tablets, USP 160 mg, 90ct	3079028	01/2020	0378-5814-77
Valsartan Tablets, USP 160 mg, 90ct	3079029	01/2020	0378-5814-77
Valsartan Tablets, USP 160 mg, 90ct	3079996	02/2020	0378-5814-77
Valsartan Tablets, USP 160 mg, 90ct	3079997	02/2020	0378-5814-77

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Product	Affected Lot	Expiration date	NDC
Valsartan Tablets, USP 160 mg, 90ct	3079998	02/2020	0378-5814-77
Valsartan Tablets, USP 160 mg, 90ct	3083635	04/2020	0378-5814-77
Valsartan Tablets, USP 160 mg, 90ct	3086715	06/2020	0378-5814-77
Valsartan Tablets, USP 160 mg, 90ct	3086716	07/2020	0378-5814-77
Valsartan Tablets, USP 160 mg, 90ct	3086717	07/2020	0378-5814-77
Valsartan Tablets, USP 160 mg, 90ct	3088623	08/2020	0378-5814-77
Valsartan Tablets, USP 320 mg, 90ct	3063783	01/2019	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3063784	01/2019	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3063785	01/2019	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3064092	01/2019	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3064093	01/2019	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3064094	01/2019	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3070349	06/2019	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3070351	06/2019	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3070352	06/2019	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3070353	06/2019	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3070354	06/2019	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3079030	01/2020	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3079031	01/2020	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3079032	01/2020	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3079033	01/2020	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3080011	02/2020	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3080224	02/2020	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3081498	03/2020	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3081500	03/2020	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3087126	07/2020	0378-5815-77
Valsartan Tablets, USP 320 mg, 90ct	3088476	08/2020	0378-5815-77
Valsartan/ Hydrochlorothiazide Tablets 80 mg/12.5 mg, 90ct	3084363	02/2019	0378-6321-77
Valsartan/ Hydrochlorothiazide Tablets 80 mg/12.5 mg, 90ct	3084364	02/2019	0378-6321-77
Valsartan/ Hydrochlorothiazide Tablets 80 mg/12.5 mg, 90ct	3093800	12/2019	0378-6321-77
Valsartan/ Hydrochlorothiazide Tablets 80 mg/12.5 mg, 500ct	3084363	02/2019	0378-6321-05
Valsartan/ Hydrochlorothiazide Tablets 80 mg/12.5 mg, 500ct	3093800	12/2019	0378-6321-05
Valsartan/ Hydrochlorothiazide Tablets 160 mg/12.5 mg, 90ct	2008880	08/2020	0378-6322-77
Valsartan/ Hydrochlorothiazide Tablets 160 mg/12.5 mg, 90ct	3084358	02/2019	0378-6322-77
Valsartan/ Hydrochlorothiazide Tablets 160 mg/12.5 mg, 90ct	3084359	02/2019	0378-6322-77
Valsartan/ Hydrochlorothiazide Tablets 160 mg/12.5 mg, 90ct	3093801	12/2019	0378-6322-77
Valsartan/ Hydrochlorothiazide Tablets 160 mg/12.5 mg, 500ct	3084359	02/2019	0378-6322-77
Valsartan/ Hydrochlorothiazide Tablets 160 mg/12.5 mg, 500ct	3084361	02/2019	0378-6322-05

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Table 1. Affected products

Product	Affected Lot	Expiration date	NDC
Valsartan/ Hydrochlorothiazide Tablets 160 mg/12.5 mg, 500ct	3093801	12/2019	0378-6322-05
Valsartan/ Hydrochlorothiazide Tablets 160 mg/12.5 mg, 500ct	3084887	02/2019	0378-6323-77
Valsartan/ Hydrochlorothiazide Tablets 160 mg/25 mg, 90ct	3093802	12/2019	0378-6323-77
Valsartan/ Hydrochlorothiazide Tablets 160 mg/25 mg, 500ct	3084887	02/2019	0378-6323-05
Valsartan/ Hydrochlorothiazide Tablets 160 mg/25 mg, 500ct	3084888	02/2019	0378-6323-05
Valsartan/ Hydrochlorothiazide Tablets 160 mg/25 mg, 500ct	3093802	12/2019	0378-6323-05
Valsartan/ Hydrochlorothiazide Tablets 320 mg/12.5 mg, 90ct	3084889	02/2019	0378-6324-77
Valsartan/ Hydrochlorothiazide Tablets 320 mg/12.5 mg, 90ct	3093803	12/2019	0378-6324-77
Valsartan/ Hydrochlorothiazide Tablets 320 mg/12.5 mg, 500ct	3084890	02/2019	0378-6324-05
Valsartan/ Hydrochlorothiazide Tablets 320 mg/12.5 mg, 500ct	3093803	12/2019	0378-6324-77
Valsartan/ Hydrochlorothiazide Tablets 320 mg/25 mg, 90ct	3084860	02/2019	0378-6325-77
Valsartan/ Hydrochlorothiazide Tablets 320 mg/25 mg, 90ct	3084861	02/2019	0378-6325-77
Valsartan/ Hydrochlorothiazide Tablets 320 mg/25 mg, 90ct	3084862	02/2019	0378-6325-77
Valsartan/ Hydrochlorothiazide Tablets 320 mg/25 mg, 90ct	3093804	12/2019	0378-6325-77
Valsartan/ Hydrochlorothiazide Tablets 320 mg/25 mg, 500ct	3084862	02/2019	0378-6325-05
Valsartan/ Hydrochlorothiazide Tablets 320 mg/25 mg, 500ct	3084863	02/2019	0378-6325-05

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 the return of the recalled product. Normal business hours are Monday through Friday 8 a.m. to 5 p.m. EST.

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For additional information visit:

https://www.fda.gov/Safety/Recalls/ucm627647.htm

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