

Urgent: Product Recall - Expansion

Valsartan-Containing Products

Recall initiated by the Distributor: Mylan Pharmaceuticals Inc.
API manufactured by: Mylan Laboratories Limited: Nashik and Aurangabad

December 04, 2018

PRODUCT

NDC	Name and Strength	Size	Lot number	Expiry
0378-1721-93	Amlodipine and Valsartan Tablets, USP 5/160 mg	Bottles of 30	3066051	March 2019
0378-1722-93	Amlodipine and Valsartan Tablets, USP 10/160 mg	Bottles of 30	3079500	January 2020
0378-1724-93	Amlodipine and Valsartan Tablets, USP 10/320 mg	Bottles of 30	3061986	November 2018
0378-1724-93	Amlodipine and Valsartan Tablets, USP 10/320 mg	Bottles of 30	3077618	November 2019
0378-1724-93	Amlodipine and Valsartan Tablets, USP 10/320 mg	Bottles of 30	3079708	January 2020
0378-1724-93	Amlodipine and Valsartan Tablets, USP 10/320 mg	Bottles of 30	3079709	January 2020
0378-5807-93	Valsartan Tablets, USP 40 mg	Bottles of 30	3061169	November 2018
0378-5813-77	Valsartan Tablets, USP 80 mg	Bottles of 90	3063782	January 2019
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3071352	July 2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3079205	January 2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3080009	February 2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3080010	February 2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3081499	March 2020
0378-6325-05	Valsartan and Hydrochlorothiazide Tablets, USP 320/25 mg	Bottles of 500	3084886	February 2019
0378-6325-77	Valsartan and Hydrochlorothiazide Tablets, USP 320/25 mg	Bottles of 90	3093804	December 2019

The expanded recall product batch numbers and expiration dates are listed below.

REASON

Mylan Pharmaceuticals Inc. is conducting a voluntary recall at the consumer level of all lots of Valsartan containing-products. These lots are being recalled due to the detected trace amounts of an impurity, N-nitrosodiethylamine (NDEA) contained in the API Valsartan, USP, manufactured by Mylan Laboratories Limited. NDEA is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes, and has been classified as a probable human carcinogen. These batches were distributed in the U.S. between March 2017 and November 2018.

Valsartan is used for the treatment of high blood pressure and for the treatment of heart failure, and to reduce cardiovascular mortality following myocardial infarction. Valsartan, in combination with Amlodipine or Hydrochlorothiazide, is used for the treatment of high blood pressure.

ACTION

Wholesaler: Immediately examine your inventory, quarantine and discontinue distribution of these lots. In addition, if you have further distributed the product, please identify your retail level customers and notify them of this product recall. Please provide a list of customers via Microsoft excel file to mylan6491@stericycle.com within 10 business days. Stericycle will notify your retail level customers that received the affected batches.

Retailer: Immediately examine your inventory, quarantine and discontinue distribution of these lots. Additionally, if you have further distributed the product, please identify the consumer and notify them immediately of this product recall. The consumer should be instructed to contact Stericycle at 1-888-406-9305 for the documentation packet to return the product to Stericycle.

Consumer: Please contact Stericycle at 1-888-406-9305 for the documentation packet to return the product to Stericycle.

Wholesaler, Retailer and Consumer: Please proceed to items 1, 2, and 3 listed below.

1. Carry out a physical count and record this data on the Business Reply Card and Packing Slip which are included.
2. Mail the postage paid Business Reply Card to the address provided.
3. Return the recalled product with the Packing Slip using the prepaid UPS Return Service shipping labels to:

Stericycle
Event # 6491
2670 Executive Drive, Suite A
Indianapolis, IN 46241

OTHER

This recall extends to the consumer level.

Credit/check will be issued for return of recalled product only.

This recall is being conducted with the knowledge of the Food and Drug Administration.

For questions regarding the recall, please call Stericycle at 1-888-406-9305.

Normal business hours are Monday through Friday 8AM to 5PM Eastern Standard Time.

Any other product returned that is not involved with this recall will be destroyed and credit will not be issued.

We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action.

The expanded recall product batch numbers and expiration dates include:

NDC	Name and Strength	Size	Lot No	Expiry
0378-1721-93	Amlodipine and Valsartan Tablets, USP 5/160 mg	Bottles of 30	3064084	January 2019
0378-1721-93	Amlodipine and Valsartan Tablets, USP 5/160 mg	Bottles of 30	3069629	May 2019
0378-1721-93	Amlodipine and Valsartan Tablets, USP 5/160 mg	Bottles of 30	3073148	August 2019
0378-1721-93	Amlodipine and Valsartan Tablets, USP 5/160 mg	Bottles of 30	3073149	August 2019
0378-1721-93	Amlodipine and Valsartan Tablets, USP 5/160 mg	Bottles of 30	3076093	October 2019
0378-1721-93	Amlodipine and Valsartan Tablets, USP 5/160 mg	Bottles of 30	3077772	November 2019
0378-1722-93	Amlodipine and Valsartan Tablets, USP 10/160 mg	Bottles of 30	3064085	January 2019
0378-1722-93	Amlodipine and Valsartan Tablets, USP 10/160 mg	Bottles of 30	3066063	March 2019
0378-1722-93	Amlodipine and Valsartan Tablets, USP 10/160 mg	Bottles of 30	3069638	May 2019
0378-1722-93	Amlodipine and Valsartan Tablets, USP 10/160 mg	Bottles of 30	3069639	June 2019
0378-1723-93	Amlodipine and Valsartan Tablets, USP 5/320 mg	Bottles of 30	3064086	January 2019
0378-1723-93	Amlodipine and Valsartan Tablets, USP 5/320 mg	Bottles of 30	3066061	March 2019
0378-1723-93	Amlodipine and Valsartan Tablets, USP 5/320 mg	Bottles of 30	3066062	March 2019
0378-1723-93	Amlodipine and Valsartan Tablets, USP 5/320 mg	Bottles of 30	3073145	September 2019
0378-1723-93	Amlodipine and Valsartan Tablets, USP 5/320 mg	Bottles of 30	3073146	September 2019
0378-1723-93	Amlodipine and Valsartan Tablets, USP 5/320 mg	Bottles of 30	3073147	September 2019
0378-1723-93	Amlodipine and Valsartan Tablets, USP 5/320 mg	Bottles of 30	3076091	November 2019
0378-1723-93	Amlodipine and Valsartan Tablets, USP 5/320 mg	Bottles of 30	3077619	November 2019
0378-1723-93	Amlodipine and Valsartan Tablets, USP 5/320 mg	Bottles of 30	3082432	March 2020
0378-1724-93	Amlodipine and Valsartan Tablets, USP 10/320 mg	Bottles of 30	3066064	March 2019
0378-1724-93	Amlodipine and Valsartan Tablets, USP 10/320 mg	Bottles of 30	3069645	June 2019
0378-1724-93	Amlodipine and Valsartan Tablets, USP 10/320 mg	Bottles of 30	3069646	June 2019
0378-1724-93	Amlodipine and Valsartan Tablets, USP 10/320 mg	Bottles of 30	3073142	September 2019
0378-1724-93	Amlodipine and Valsartan Tablets, USP 10/320 mg	Bottles of 30	3073143	September 2019
0378-1724-93	Amlodipine and Valsartan Tablets, USP 10/320 mg	Bottles of 30	3073144	September 2019
0378-1724-93	Amlodipine and Valsartan Tablets, USP 10/320 mg	Bottles of 30	3077617	November 2019

NDC	Name and Strength	Size	Lot No	Expiry
0378-5807-93	Valsartan Tablets, USP 40 mg	Bottles of 30	3063780	January 2019
0378-5807-93	Valsartan Tablets, USP 40 mg	Bottles of 30	3074879	October 2019
0378-5807-93	Valsartan Tablets, USP 40 mg	Bottles of 30	3086684	June 2020
0378-5807-93	Valsartan Tablets, USP 40 mg	Bottles of 30	3086687	June 2020
0378-5813-77	Valsartan Tablets, USP 80 mg	Bottles of 90	3065445	February 2019
0378-5813-77	Valsartan Tablets, USP 80 mg	Bottles of 90	3074880	October 2019
0378-5813-77	Valsartan Tablets, USP 80 mg	Bottles of 90	3074883	October 2019
0378-5813-77	Valsartan Tablets, USP 80 mg	Bottles of 90	3086688	June 2020
0378-5813-77	Valsartan Tablets, USP 80 mg	Bottles of 90	3086689	June 2020
0378-5813-77	Valsartan Tablets, USP 80 mg	Bottles of 90	3086710	June 2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3069019	May 2019
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3069020	May 2019
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3069021	May 2019
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3069022	May 2019
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3071354	July 2019
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3071355	July 2019
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3071357	July 2019
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3079023	January 2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3079027	January 2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3079028	January 2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3079029	January 2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3079996	February 2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3079997	February 2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3079998	February 2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3083635	April 2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3086715	June 2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3086716	July 2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3086717	July 2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3088623	August 2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3063783	January 2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3063784	January 2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3063785	January 2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3064092	January 2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3064093	January 2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3064094	January 2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3070349	June 2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3070350	June 2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3070351	June 2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3070352	June 2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3070353	June 2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3070354	June 2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3079030	January 2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3079031	January 2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3079032	January 2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3079033	January 2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3080011	February 2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3080224	February 2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3081498	March 2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3081500	March 2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3087126	July 2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3088476	August 2020

NDC	Name and Strength	Size	Lot No	Expiry
0378-6321-77	Valsartan and Hydrochlorothiazide Tablets, USP 80/12.5 mg	Bottles of 90	3084363	February 2019
0378-6321-77	Valsartan and Hydrochlorothiazide Tablets, USP 80/12.5 mg	Bottles of 90	3084364	February 2019
0378-6321-77	Valsartan and Hydrochlorothiazide Tablets, USP 80/12.5 mg	Bottles of 90	3093800	December 2019
0378-6321-05	Valsartan and Hydrochlorothiazide Tablets, USP 80/12.5 mg	Bottles of 500	3084363	February 2019
0378-6321-05	Valsartan and Hydrochlorothiazide Tablets, USP 80/12.5 mg	Bottles of 500	3093800	December 2019
0378-6322-77	Valsartan and Hydrochlorothiazide Tablets, USP 160/12.5 mg	Bottles of 90	2008880	August 2020
0378-6322-77	Valsartan and Hydrochlorothiazide Tablets, USP 160/12.5 mg	Bottles of 90	3084358	February 2019
0378-6322-77	Valsartan and Hydrochlorothiazide Tablets, USP 160/12.5 mg	Bottles of 90	3084359	February 2019
0378-6322-77	Valsartan and Hydrochlorothiazide Tablets, USP 160/12.5 mg	Bottles of 90	3093801	December 2019
0378-6322-05	Valsartan and Hydrochlorothiazide Tablets, USP 160/12.5 mg	Bottles of 500	3084359	February 2019
0378-6322-05	Valsartan and Hydrochlorothiazide Tablets, USP 160/12.5 mg	Bottles of 500	3084361	February 2019
0378-6322-05	Valsartan and Hydrochlorothiazide Tablets, USP 160/12.5 mg	Bottles of 500	3093801	December 2019
0378-6323-77	Valsartan and Hydrochlorothiazide Tablets, USP 160/25 mg	Bottles of 90	3084887	February 2019
0378-6323-77	Valsartan and Hydrochlorothiazide Tablets, USP 160/25 mg	Bottles of 90	3093802	December 2019
0378-6323-05	Valsartan and Hydrochlorothiazide Tablets, USP 160/25 mg	Bottles of 500	3084887	February 2019
0378-6323-05	Valsartan and Hydrochlorothiazide Tablets, USP 160/25 mg	Bottles of 500	3084888	February 2019
0378-6323-05	Valsartan and Hydrochlorothiazide Tablets, USP 160/25 mg	Bottles of 500	3093802	December 2019
0378-6324-77	Valsartan and Hydrochlorothiazide Tablets, USP 320/12.5 mg	Bottles of 90	3084889	February 2019
0378-6324-77	Valsartan and Hydrochlorothiazide Tablets, USP 320/12.5 mg	Bottles of 90	3093803	December 2019
0378-6324-05	Valsartan and Hydrochlorothiazide Tablets, USP 320/12.5 mg	Bottles of 500	3084890	February 2019
0378-6324-05	Valsartan and Hydrochlorothiazide Tablets, USP 320/12.5 mg	Bottles of 500	3093803	December 2019
0378-6325-77	Valsartan and Hydrochlorothiazide Tablets, USP 320/25 mg	Bottles of 90	3084860	February 2019
0378-6325-77	Valsartan and Hydrochlorothiazide Tablets, USP 320/25 mg	Bottles of 90	3084861	February 2019
0378-6325-77	Valsartan and Hydrochlorothiazide Tablets, USP 320/25 mg	Bottles of 90	3084862	February 2019
0378-6325-05	Valsartan and Hydrochlorothiazide Tablets, USP 320/25 mg	Bottles of 500	3084862	February 2019
0378-6325-05	Valsartan and Hydrochlorothiazide Tablets, USP 320/25 mg	Bottles of 500	3084863	February 2019
0378-6325-05	Valsartan and Hydrochlorothiazide Tablets, USP 320/25 mg	Bottles of 500	3093804	December 2019