Urgent: Product Recall

Valsartan Containing-Products

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

November 21, 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

REASON

Mylan Pharmaceuticals Inc. is conducting a voluntary recall at the consumer level of the above referenced 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 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
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.