Company Announcement

Mylan Initiates Voluntary Nationwide Recall of 15 Lots of Valsartan Tablets, USP, Amlodipine and Valsartan Tablets, USP, and Valsartan and Hydrochlorothiazide Tablets, USP, Due to the Detection of Trace Amounts of NDEA (N-Nitrosodiethylamine) Impurity Found in the Active Pharmaceutical Ingredient

For Immediate Release

November 20, 2018

Contact

Consumers

888-406-9305

Announcement

View Product Photos

Mylan N.V. (NASDAQ: MYL) today announced that its U.S. based Mylan Pharmaceuticals business is conducting a voluntary nationwide recall to the consumer level of select lots of Valsartan-containing products, including six lots of Amlodipine and Valsartan Tablets, USP (including the 5mg/160mg, 10mg/160mg, and 10mg/320mg strengths),

seven lots of Valsartan Tablets, USP (including 40 mg, 80 mg, 160 mg, and 320 mg strengths), and two lots of Valsartan and Hydrochlorothiazide Tablets, USP 320mg/25mg strength. These products are being recalled due to 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 according to the International Agency for Research on Cancer (IARC).

The finished products are manufactured by Mylan Pharmaceuticals Inc. and Mylan Laboratories Limited. These batches were distributed in the U.S. between March 2017 and November 2018. The recalled batches are as follows:

NDC	Product Description	Strength	Size	Lot Number	Expiry
0378-1721-93	Amlodipine and Valsartan Tablets, USP	5mg/160mg	Bottles of 30	3066051	3/2019
0378-1722-93	Amlodipine and Valsartan Tablets, USP	10mg/160mg	Bottles of 30	3079500	1/2020
0378-1724-93	Amlodipine and Valsartan Tablets, USP	10mg/320mg	Bottles of 30	3061986	11/2018
0378-1724-93	Amlodipine and Valsartan Tablets, USP	10mg/320mg	Bottles of 30	3079709	1/2020
0378-1724-93	Amlodipine and Valsartan Tablets, USP	10mg/320mg	Bottles of 30	3077618	11/2019
0378-1724-93	Amlodipine and Valsartan Tablets, USP	10mg/320mg	Bottles of 30	3079708	1/2020
0378-5813-77	Valsartan Tablets, USP	80mg	Bottles of 90	3063782	1/2019
0378-5814-77	Valsartan Tablets, USP	160mg	Bottles of 90	3071352	7/2019
0378-5807-93	Valsartan Tablets, USP	40mg	Bottles of 30	3061169	11/2018
0378-5815-77	Valsartan Tablets, USP	320mg	Bottles of 90	3081499	3/2020
0378-5815-77	Valsartan Tablets, USP	320mg	Bottles of 90	3080009	2/2020
0378-5815-77	Valsartan Tablets, USP	320mg	Bottles of 90	3080010	2/2020
0378-5815-77	Valsartan Tablets, USP	320mg	Bottles of 90	3079205	1/2020
0378-6325-05	Valsartan and Hydrochlorothiazide Tablets, USP	320mg/25mg	Bottles of 500	3084886	2/2019
0378-6325-05	Valsartan and Hydrochlorothiazide Tablets, USP	320mg/25mg	Bottles of 500	3093804	12/2019

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. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. Patients who are on valsartan should continue taking their medication, as the risk of harm to the patient's health may be higher if the treatment is stopped immediately without any alternative treatment.

Mylan is notifying its distributors and customers by letter and is arranging for return of all recalled products. Wholesalers, retailers and consumers that are in possession of recalled product should 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.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to using these drug products.

- Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. Complete and submit the report Online: **www.fda.gov/medwatch/report.htm (http://www.fda.gov/medwatch/report.htm)**
- Regular Mail or Fax: Download form **www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/MedWatch/getforms.htm)** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

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

About Mylan
Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which more than 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our approximately 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at **Mylan.com (http://www.mylan.com)**.

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Product Photos










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