Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Mylan Expands Its Voluntary Nationwide Recall of Valsartan Tablets, USP, Amlodipine and Valsartan Tablets, USP, and Valsartan and Hydrochlorothiazide Tablets, USP, to all Lots Within Expiry Due to The Detection of Trace Amounts of NDEA (N-Nitrosodiethylamine) Impurity Found in the Active Pharmaceutical Ingredient

For Immediate Release

December 4, 2018

Contact

Consumers

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Announcement

View Product Photos

Mylan N.V. (http://www.mylan.com/) (NASDAQ: MYL) today announced that its U.S. based Mylan Pharmaceuticals business is expanding its consumer-level voluntary nationwide recall to include all lots of Valsartan-containing products within expiry. The 104 additional lots include 26 lots of Amlodipine and Valsartan Tablets, USP (including the 5mg/160mg, 10mg/160mg, 5mg/320mg and 10mg/320mg strengths), 51 lots of Valsartan Tablets, USP (including 40 mg, 80 mg, 160 mg and 320 mg strengths), and 27 lots of Valsartan and Hydrochlorothiazide Tablets, USP (80mg/12.5mg, 160mg/12.5mg, 160mg/25mg, 320mg/12.5mg and 320mg/25mg strengths).

Out of an abundance of caution, 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 expanded recalled batches are as follows:

NDC	Name and Strength	Size	Lot No	Expiry
0378-1721-93	Amlodipine and Valsartan Tablets, USP 5/160 mg	Bottles of 30	3064084	1/2019
0378-1721-93	Amlodipine and Valsartan Tablets, USP 5/160 mg	Bottles of 30	3069629	5/2019
0378-1721-93	Amlodipine and Valsartan Tablets, USP 5/160 mg	Bottles of 30	3073148	8/2019
0378-1721-93	Amlodipine and Valsartan Tablets, USP 5/160 mg	Bottles of 30	3073149	8/2019
0378-1721-93	Amlodipine and Valsartan Tablets, USP 5/160 mg	Bottles of 30	3076093	10/2019
0378-1721-93	Amlodipine and Valsartan Tablets, USP 5/160 mg	Bottles of 30	3077772	11/2019
0378-1722-93	Amlodipine and Valsartan Tablets, USP 10/160 mg	Bottles of 30	3064085	1/2019
0378-1722-93	Amlodipine and Valsartan Tablets, USP 10/160 mg	Bottles of 30	3066063	3/2019
0378-1722-93	Amlodipine and Valsartan Tablets, USP 10/160 mg	Bottles of 30	3069638	5/2019
0378-1722-93	Amlodipine and Valsartan Tablets, USP 10/160 mg	Bottles of 30	3069639	6/2019
0378-1723-93	Amlodipine and Valsartan Tablets, USP 5/320 mg	Bottles of 30	3064086	1/2019
0378-1723-93	Amlodipine and Valsartan Tablets, USP 5/320 mg	Bottles of 30	3066061	3/2019
0378-1723-93	Amlodipine and Valsartan Tablets, USP 5/320 mg	Bottles of 30	3066062	3/2019
0378-1723-93	Amlodipine and Valsartan Tablets, USP 5/320 mg	Bottles of 30	3073145	9/2019
0378-1723-93	Amlodipine and Valsartan Tablets, USP 5/320 mg	Bottles of 30	3073146	9/2019

NDC	Name and Strength	Size	Lot No	Expiry
0378-1723-93	Amlodipine and Valsartan Tablets, USP 5/320 mg	Bottles of 30	3073147	9/2019
0378-1723-93	Amlodipine and Valsartan Tablets, USP 5/320 mg	Bottles of 30	3076091	11/2019
0378-1723-93	Amlodipine and Valsartan Tablets, USP 5/320 mg	Bottles of 30	3077619	11/2019
0378-1723-93	Amlodipine and Valsartan Tablets, USP 5/320 mg	Bottles of 30	3082432	3/2020
0378-1724-93	Amlodipine and Valsartan Tablets, USP 10/320 mg	Bottles of 30	3066064	3/2019
0378-1724-93	Amlodipine and Valsartan Tablets, USP 10/320 mg	Bottles of 30	3069645	6/2019
0378-1724-93	Amlodipine and Valsartan Tablets, USP 10/320 mg	Bottles of 30	3069646	6/2019
0378-1724-93	Amlodipine and Valsartan Tablets, USP 10/320 mg	Bottles of 30	3073142	9/2019
0378-1724-93	Amlodipine and Valsartan Tablets, USP 10/320 mg	Bottles of 30	3073143	9/2019
0378-1724-93	Amlodipine and Valsartan Tablets, USP 10/320 mg	Bottles of 30	3073144	9/2019
0378-1724-93	Amlodipine and Valsartan Tablets, USP 10/320 mg	Bottles of 30	3077617	11/2019

NDC	Name and Strength	Size	Lot No	Expiry
0378-5807-93	Valsartan Tablets, USP 40 mg	Bottles of 30	3063780	1/2019
0378-5807-93	Valsartan Tablets, USP 40 mg	Bottles of 30	3074879	10/2019
0378-5807-93	Valsartan Tablets, USP 40 mg	Bottles of 30	3086684	6/2020
0378-5807-93	Valsartan Tablets, USP 40 mg	Bottles of 30	3086687	6/2020
0378-5813-77	Valsartan Tablets, USP 80 mg	Bottles of 90	3065445	2/2019
0378-5813-77	Valsartan Tablets, USP 80 mg	Bottles of 90	3074880	10/2019
0378-5813-77	Valsartan Tablets, USP 80 mg	Bottles of 90	3074883	10/2019
0378-5813-77	Valsartan Tablets, USP 80 mg	Bottles of 90	3086688	6/2020
0378-5813-77	Valsartan Tablets, USP 80 mg	Bottles of 90	3086689	6/2020
0378-5813-77	Valsartan Tablets, USP 80 mg	Bottles of 90	3086710	6/2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3069019	5/2019
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3069020	5/2019
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3069021	5/2019
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3069022	5/2019

NDC	Name and Strength	Size	Lot No	Expiry
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3071354	7/2019
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3071355	7/2019
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3071357	7/2019
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3079023	1/2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3079027	1/2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3079028	1/2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3079029	1/2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3079996	2/2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3079997	2/2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3079998	2/2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3083635	4/2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3086715	6/2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3086716	7/2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3086717	7/2020
0378-5814-77	Valsartan Tablets, USP 160 mg	Bottles of 90	3088623	8/2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3063783	1/2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3063784	1/2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3063785	1/2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3064092	1/2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3064093	1/2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3064094	1/2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3070349	6/2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3070350	6/2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3070351	6/2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3070352	6/2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3070353	6/2019
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3070354	6/2019

NDC	Name and Strength	Size	Lot No	Expiry
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3079030	1/2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3079031	1/2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3079032	1/2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3079033	1/2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3080011	2/2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3080224	2/2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3081498	3/2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3081500	3/2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3087126	7/2020
0378-5815-77	Valsartan Tablets, USP 320 mg	Bottles of 90	3088476	8/2020

NDC	Name and Strength	Size	Lot No	Expiry
0378-6321-77	Valsartan and Hydrochlorothiazide Tablets, USP 80/12.5 mg	Bottles of 90	3084363	2/2019
0378-6321-77	Valsartan and Hydrochlorothiazide Tablets, USP 80/12.5 mg	Bottles of 90	3084364	2/2019
0378-6321-77	Valsartan and Hydrochlorothiazide Tablets, USP 80/12.5 mg	Bottles of 90	3093800	12/2019
0378-6321-05	Valsartan and Hydrochlorothiazide Tablets, USP 80/12.5 mg	Bottles of 500	3084363	2/2019
0378-6321-05	Valsartan and Hydrochlorothiazide Tablets, USP 80/12.5 mg	Bottles of 500	3093800	12/2019
0378-6322-77	Valsartan and Hydrochlorothiazide Tablets, USP 160/12.5 mg	Bottles of 90	2008880	8/2020
0378-6322-77	Valsartan and Hydrochlorothiazide Tablets, USP 160/12.5 mg	Bottles of 90	3084358	2/2019
0378-6322-77	Valsartan and Hydrochlorothiazide Tablets, USP 160/12.5 mg	Bottles of 90	3084359	2/2019
0378-6322-77	Valsartan and Hydrochlorothiazide Tablets, USP 160/12.5 mg	Bottles of 90	3093801	12/2019
0378-6322-05	Valsartan and Hydrochlorothiazide Tablets, USP 160/12.5 mg	Bottles of 500	3084359	2/2019
0378-6322-05	Valsartan and Hydrochlorothiazide Tablets, USP 160/12.5 mg	Bottles of 500	3084361	2/2019
0378-6322-05	Valsartan and Hydrochlorothiazide Tablets, USP 160/12.5 mg	Bottles of 500	3093801	12/2019
0378-6323-77	Valsartan and Hydrochlorothiazide Tablets, USP 160/25 mg	Bottles of 90	3084887	2/2019
0378-6323-77	Valsartan and Hydrochlorothiazide Tablets, USP 160/25 mg	Bottles of 90	3093802	12/2019
0378-6323-05	Valsartan and Hydrochlorothiazide Tablets, USP 160/25 mg	Bottles of 500	3084887	2/2019

NDC	Name and Strength	Size	Lot No	Expiry
0378-6323-05	Valsartan and Hydrochlorothiazide Tablets, USP 160/25 mg	Bottles of 500	3084888	2/2019
0378-6323-05	Valsartan and Hydrochlorothiazide Tablets, USP 160/25 mg	Bottles of 500	3093802	12/2019
0378-6324-77	Valsartan and Hydrochlorothiazide Tablets, USP 320/12.5 mg	Bottles of 90	3084889	2/2019
0378-6324-77	Valsartan and Hydrochlorothiazide Tablets, USP 320/12.5 mg	Bottles of 90	3093803	12/2019
0378-6324-05	Valsartan and Hydrochlorothiazide Tablets, USP 320/12.5 mg	Bottles of 500	3084890	2/2019
0378-6324-05	Valsartan and Hydrochlorothiazide Tablets, USP 320/12.5 mg	Bottles of 500	3093803	12/2019
0378-6325-77	Valsartan and Hydrochlorothiazide Tablets, USP 320/25 mg	Bottles of 90	3084860	2/2019
0378-6325-77	Valsartan and Hydrochlorothiazide Tablets, USP 320/25 mg	Bottles of 90	3084861	2/2019
0378-6325-77	Valsartan and Hydrochlorothiazide Tablets, USP 320/25 mg	Bottles of 90	3084862	2/2019
0378-6325-77	Valsartan and Hydrochlorothiazide Tablets, USP 320/25 mg	Bottles of 90	3093804	12/2019
0378-6325-05	Valsartan and Hydrochlorothiazide Tablets, USP 320/25 mg	Bottles of 500	3084862	2/2019
0378-6325-05	Valsartan and Hydrochlorothiazide Tablets, USP 320/25 mg	Bottles of 500	3084863	2/2019

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.

Initial Press Release (/Safety/Recalls/ucm626367.htm)

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