

Mylan Initiates Voluntary Nationwide Recall of 15 Lots of Valsartan Tablets, USP, Amlodipine and Valsartan Tablets, USP, and Valsartan and Hydrochlorothiazide Tablets

November 20, 2018

Mylan N.V. announced that its United States (US) 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 5 mg/160 mg, 10 mg/160 mg, and 10 mg/320 mg 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 320 mg/25 mg 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).

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.

The finished products are manufactured by Mylan Pharmaceuticals Inc. and Mylan Laboratories Limited. These batches were distributed in the US 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	5 mg/160 mg	Bottles of 30	3066051	3/2019
0378-1722-93	Amlodipine and Valsartan Tablets, USP	10 mg/160 mg	Bottles of 30	3079500	1/2020
0378-1724-93	Amlodipine and Valsartan Tablets, USP	10 mg/320 mg	Bottles of 30	3061986	11/2018
0378-1724-93	Amlodipine and Valsartan Tablets, USP	10 mg/320 mg	Bottles of 30	3079709	1/2020
0378-1724-93	Amlodipine and Valsartan Tablets, USP	10 mg/320 mg	Bottles of 30	3077618	11/2019

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

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.
- Regular Mail or Fax: Download form 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 US Food and Drug Administration.

Read the safety alert: [FDA Link](#)

Product Photos

<p>Each film-coated tablet contains: Amlodipine besylate, USP 6.94 mg (equivalent to Amlodipine) 5 mg Valsartan, USP 160 mg</p> <p>Usual Dosage: See accompanying prescribing information.</p> <p>Keep this and all medication out of the reach of children.</p> <p>Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]</p> <p>Protect from moisture.</p> <p>Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A. Made in India</p> <p>Mylan® Mylan.com</p>	<p>NDC 0378-1721-93</p> <p>Amlodipine and Valsartan</p> <p>Tablets, USP</p> <p>5 mg/ 160 mg</p> <p>MX 1</p> <p>Mylan®</p> <p>Rx only 30 Tablets</p>	<p>75059571</p> <p>3 0378-1721-93 6</p> <p>Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure. Keep container tightly closed.</p> <p>Code No.: MN/DRUGS/25-NKD/89</p> <p>(40 x 15 mm) Varnish Free area for Variable Data Coding</p>

<p>Each film-coated tablet contains: Amlodipine besylate, USP 13.88 mg (equivalent to Amlodipine) 10 mg Valsartan, USP 160 mg</p> <p>Usual Dosage: See accompanying prescribing information.</p> <p>Keep this and all medication out of the reach of children.</p> <p>Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]</p> <p>Protect from moisture.</p> <p>Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A. Made in India</p> <p>Mylan® Mylan.com</p>	<p>NDC 0378-1722-93</p> <p>Amlodipine and Valsartan</p> <p>Tablets, USP</p> <p>10 mg/ 160 mg</p> <p>MX 2</p> <p>Mylan®</p> <p>Rx only 30 Tablets</p>	<p>75059573</p> <p>3 0378-1722-93 3</p> <p>Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure. Keep container tightly closed.</p> <p>Code No.: MN/DRUGS/25-NKD/89</p> <p>(40 x 15 mm) Varnish Free area for Variable Data Coding</p>

<p>Each film-coated tablet contains: Amlodipine besylate, USP 13.88 mg (equivalent to Amlodipine) 10 mg Valsartan, USP 320 mg</p> <p>Usual Dosage: See accompanying prescribing information.</p> <p>Keep this and all medication out of the reach of children.</p> <p>Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]</p> <p>Protect from moisture.</p> <p>Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A. Made in India</p> <p>Mylan® Mylan.com</p>	<p>NDC 0378-1724-93</p> <p>Amlodipine and Valsartan</p> <p>Tablets, USP</p> <p>10 mg/ 320 mg</p> <p>MX 4-4</p> <p>Mylan®</p> <p>Rx only 30 Tablets</p>	<p>75059574</p> <p>3 0378-1724-93 7</p> <p>Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure. Keep container tightly closed.</p> <p>Code No.: MN/DRUGS/25-NKD/89</p> <p>(40 x 15 mm) Varnish Free area for Variable Data Coding</p>

<p>Each film-coated scored tablet contains: Valsartan, USP 40 mg</p> <p>Usual Dosage: See accompanying prescribing information.</p> <p>Keep this and all medication out of the reach of children.</p> <p>Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]</p> <p>Protect from moisture.</p> <p>Manufactured for: Mylan Pharmaceuticals Inc. Morgantown, WV 26505 U.S.A. Made in India</p> <p>Mylan® Mylan.com</p>	<p>NDC 0378-5807-93</p> <p>Valsartan</p> <p>Tablets, USP</p> <p>40 mg</p> <p>Mylan®</p> <p>Rx only 30 Tablets</p>	<p>75061137</p> <p>3 0378-5807-93 3</p> <p>Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure. Keep container tightly closed.</p> <p>Code No.: MN/DRUGS/AD/089</p> <p>VARNISH FREE AREA Prompt "LOT" & "EXP" will be printed together with variable data coding online.</p>

Each film-coated scored tablet contains:
Valsartan, USP 40 mg

Usual Dosage: See accompanying prescribing information.

Keep this and all medication out of the reach of children.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Protect from moisture.

Manufactured for:
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.
Made in India

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NDC 0378-5807-93

Valsartan Tablets, USP

40 mg



Mylan®

Rx only 30 Tablets

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure. Keep container tightly closed.
Code No.: MH/DRUGS/25-NKD/89

(40 x 15 mm)
Varnish Free area for Variable Data Coding

75061220

Each film-coated tablet contains:
Valsartan, USP 80 mg

Usual Dosage: See accompanying prescribing information.

Keep this and all medication out of the reach of children.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Protect from moisture.


Manufactured for:
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.
Made in India

Mylan® | Mylan.com

NDC 0378-5813-77

Valsartan Tablets, USP

80 mg



Mylan®

Rx only 90 Tablets

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure. Keep container tightly closed.
Code No.: MH/DRUGS/25-NKD/89

(40 x 15 mm)
Varnish Free area for Variable Data Coding

75061221

Each film-coated tablet contains:
Valsartan, USP 80 mg

Usual Dosage: See accompanying prescribing information.

Keep this and all medication out of the reach of children.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Protect from moisture.


Manufactured for:
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.
Made in India

Mylan® | Mylan.com

NDC 0378-5813-77

Valsartan Tablets, USP

80 mg



Mylan®

Rx only 90 Tablets

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure. Keep container tightly closed.
Code No.: MH/DRUGS/AD/089

VARNISH FREE AREA
Prompt "LOT" & "EXP" will be printed together with variable data coding online.

75061138

Each film-coated tablet contains:
Valsartan, USP 160 mg

Usual Dosage: See accompanying prescribing information.

Keep this and all medication out of the reach of children.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Protect from moisture.

Manufactured for:
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.
Made in India

Mylan® | Mylan.com

NDC 0378-5814-77

Valsartan Tablets, USP

160 mg



Mylan®

Rx only 90 Tablets

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure. Keep container tightly closed.
Code No.: MH/DRUGS/25-NKD/89

(40 x 15 mm)
Varnish Free area for Variable Data Coding

75061222

Each film-coated tablet contains:
Valsartan, USP 160 mg

Usual Dosage: See accompanying prescribing information.

Keep this and all medication out of the reach of children.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Protect from moisture.


Manufactured for:
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.
Made in India

Mylan® | Mylan.com

NDC 0378-5814-77

Valsartan Tablets, USP

160 mg



Mylan®

Rx only 90 Tablets

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure. Keep container tightly closed.
Code No.: MH/DRUGS/AD/089

VARNISH FREE AREA
Prompt "LOT" & "EXP" will be printed together with variable data coding online.

75061139

Each film-coated tablet contains:
Valsartan, USP 320 mg

Usual Dosage: See accompanying prescribing information.

Keep this and all medication out of the reach of children.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Protect from moisture.

Manufactured for:
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.
Made in India

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NDC 0378-5815-77

**Valsartan
Tablets, USP**

320 mg

Mylan®

Rx only 90 Tablets

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure. Keep container tightly closed. Code No.: MH/DRUGS/25-NKD/89

(40 x 15 mm)
Varnish Free area for Variable Data Coding

75061223

Each film-coated tablet contains:
Valsartan, USP 320 mg

Usual Dosage: See accompanying prescribing information.

Keep this and all medication out of the reach of children.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Protect from moisture.

Manufactured for:
Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.
Made in India

Mylan® | Mylan.com

NDC 0378-5815-77

**Valsartan
Tablets, USP**

320 mg

Mylan®

Rx only 90 Tablets

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure. Keep container tightly closed. Code No.: MH/DRUGS/AD/089

VARNISH FREE AREA
Prompt "LOT" & "EXP" will be printed together with variable data coding online.

75061230

Each film-coated tablet contains:
Valsartan, USP 320 mg
Hydrochlorothiazide, USP 25 mg

NDC 0378-6325-05

**Valsartan and
Hydrochlorothiazide
Tablets, USP**

320 mg/25 mg

Mylan®

Rx only 500 Tablets

Dispense in a tight, light-resistant container as defined in the USP using a child-resistant closure. Keep container tightly closed. **Keep this and all medication out of the reach of children.** Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.] **Protect from moisture and heat.** **Usual Dosage:** See accompanying prescribing information. This container is not intended for dispensing for household use.

PHARMACIST: Dispense the Patient Information Leaflet provided separately to each patient.

Mylan Pharmaceuticals Inc.
Morgantown, WV 26505 U.S.A.

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75061230