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.

Aurobindo Pharma USA, Inc. Initiates Voluntary Nationwide Consumer Level Recall of 80 Lots of Amlodipine Valsartan Tablets USP, Valsartan HCTZ Tablets, USP and Valsartan Tablets USP, Due to the Detection of NDEA (N-Nitrosodiethylamine) Impurity

For Immediate Release

December 31, 2018

Contact

Consumers

Aurobindo Pharma USA
pvg@aurobindousa.com (mailto:pvg@aurobindousa.com)
1-866-850-2876 Option 2

Consumers

Inmar\CLS-Medturn
rxrecalls@inmar.com (mailto:rxrecalls@inmar.com)
1-877-208-2407

Announcement

View Product Photos

Aurobindo Pharma USA, Inc. is conducting a voluntary recall of 80 lots of **Amlodipine Valsartan Tablets USP, Valsartan HCTZ Tablets, USP and Valsartan Tablets USP** to the consumer level due to the detection of trace amounts of an unexpected impurity found in the finished drug product. The impurity detected in the finished drug product is N-nitrosodiethylamine (NDEA), which 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 as per International Agency for Research on Cancer (IARC) classification. To date, Aurobindo Pharma USA, Inc. has not received any reports of adverse events related to this recall.

Amlodipine Valsartan Tablets USP, Valsartan HCTZ Tablets, USP and Valsartan Tablets USP are indicated to control high blood pressure and for the treatment of heart failure. Patients who prescribed **Amlodipine Valsartan Tablets USP, Valsartan HCTZ Tablets, USP and Valsartan Tablets USP** 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. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication.

The products subject to recall are listed below and packaged in bottles. The product can be identified by checking the product name, manufacturer details and batch or lot number on the bottle containing these products.

NDC	Name and strength	Count	Lot number	Expiry
65862-737-30	Amlodipine and Valsartan Tablets USP5mg/160mg	30	VESA17013-A	10/2019
65862-737-30	Amlodipine and Valsartan Tablets USP5mg/160mg	30	VESA17014-A	10/2019
65862-737-30	Amlodipine and Valsartan Tablets USP5mg/160mg	30	VESA18001-A	12/2019
65862-737-30	Amlodipine and Valsartan Tablets USP5mg/160mg	30	VESA18002-A	12/2019
65862-739-30	Amlodipine and Valsartan Tablets USP10mg/160mg	30	VFSA17008-A	10/2019
65862-739-30	Amlodipine and Valsartan Tablets USP10mg/160mg	30	VFSA17010-A	10/2019
65862-739-30	Amlodipine and Valsartan Tablets USP10mg/160mg	30	VFSA18002-A	01/2020
65862-739-30	Amlodipine and Valsartan Tablets USP10mg/160mg	30	VFSA18003-A	01/2020
65862-739-30	Amlodipine and Valsartan Tablets USP10mg/160mg	30	VFSA18007-A	03/2020
65862-739-30	Amlodipine and Valsartan Tablets USP10mg/160mg	30	VFSA18008-A	03/2020
65862-740-30	Amlodipine and Valsartan Tablets USP10mg /320mg	30	VKSA17008-A	05/2019
65862-740-30	Amlodipine and Valsartan Tablets USP10mg /320mg	30	VKSA17014-A	10/2019
65862-740-30	Amlodipine and Valsartan Tablets USP10mg /320mg	30	VKSA17015-A	10/2019
65862-740-30	Amlodipine and Valsartan Tablets USP10mg /320mg	30	VKSA17016-A	10/2019
65862-740-30	Amlodipine and Valsartan Tablets USP10mg /320mg	30	VKSA17017-A	10/2019
65862-740-30	Amlodipine and Valsartan Tablets USP10mg /320mg	30	VKSA18002-A	01/2020
65862-740-30	Amlodipine and Valsartan Tablets USP10mg /320mg	30	VKSA18004-A	01/2020

NDC	Name and strength	Count	Lot number	Expiry
65862-738-30	Amlodipine and Valsartan Tablets USP5mg /320mg	30	VMSA17012-A	11/2019
65862-738-30	Amlodipine and Valsartan Tablets USP5mg /320mg	30	VMSA17013-A	11/2019
65862-738-30	Amlodipine and Valsartan Tablets USP5mg /320mg	30	VMSA17014-A	11/2019
65862-738-30	Amlodipine and Valsartan Tablets USP5mg /320mg	30	VMSA17015-A	11/2019
65862-738-30	Amlodipine and Valsartan Tablets USP5mg /320mg	30	VMSA17016-A	11/2019
65862-738-30	Amlodipine and Valsartan Tablets USP5mg /320mg	30	VMSA17017-A	11/2019
65862-739-30	Amlodipine and Valsartan Tablets USP10mg/160mg	30	VFSA17009-A	10/2019
65862-740-30	Amlodipine and Valsartan Tablets USP 10mg /320mg	30	VKSA18005-A	03/2020
65862-740-30	Amlodipine and Valsartan Tablets USP 10mg /320mg	30	VKSA18001-A	01/2020
65862-550-90	Valsartan and Hydrochlorothiazide tablets & USP 320mg/12.5mg	90	HRSA17033-A	10/2020
65862-550-90	Valsartan and Hydrochlorothiazide tablets & USP 320mg/12.5mg	90	HRSA17034-A	10/2020
65862-550-90	Valsartan and Hydrochlorothiazide tablets & USP 320mg/12.5mg	90	HRSA17035-A	10/2020
65862-550-90	Valsartan and Hydrochlorothiazide tablets & USP 320mg/12.5mg	90	HRSA17036-A	10/2020
65862-550-90	Valsartan and Hydrochlorothiazide tablets & USP 320mg/12.5mg	90	HRSA17037-A	10/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg	90	HTSA17033-A	10/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg	90	HTSA17034-A	10/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg	90	HTSA17035-A	10/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg	90	HTSA17036-A	10/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg	90	HTSA17040-A	10/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg	90	HTSA17041-A	11/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg	90	HTSA17042-A	11/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP160mg/12.5mg	90	HTSA17043-A	11/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17049-A	08/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17054-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17055-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17056-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17057-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17058-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17059-A	10/2020

NDC	Name and strength	Count	Lot number	Expiry
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17060-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17062-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17066-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17067-A	11/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17068-A	11/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17069-A	11/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB18001-A	12/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB18002-A	12/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB18003-A	12/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB18004-A	12/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB18005-A	12/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB18006-A	12/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB18007-A	12/2020
65862-547-90	Valsartan and Hydrochlorothiazide tablets USP 80mg/12.5mg	90	HVSA17011-A	11/2020
65862-547-90	Valsartan and Hydrochlorothiazide tablets USP 80mg/12.5mg	90	HVSA17012-A	11/2020
65862-547-90	Valsartan and Hydrochlorothiazide tablets USP 80mg/12.5mg	90	HVSA18001-A	12/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB17023-A	08/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB17036-A	11/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB17037-A	11/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB17038-A	11/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB17039-A	11/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB17040-B	11/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB18001-A	12/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB18002-A	12/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB18003-A	12/2020
65862-549-90	Valsartan and Hydrochlorothiazide tablets USP 160mg/25mg	90	HVSB18004-A	12/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP 160mg/12.5mg	90	HTSA17037-A	10/2020
65862-548-90	Valsartan and Hydrochlorothiazide Tablets USP 160mg/12.5mg	90	HTSA17039-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17063-A	10/2020

NDC	Name and strength	Count	Lot number	Expiry
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17064-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP 320mg/25mg	90	HTSB17065-A	10/2020
65862-551-90	Valsartan and Hydrochlorothiazide Tablets USP & 320/25mg	90	HTSB18029-A	03/2021
65862-573-90	Valsartan Tablets USP 320mg	90	VUSD17008-A	07/2019
65862-573-90	Valsartan Tablets USP 320mg	90	VUSD17009-A	09/2019

Amlodipine Valsartan Tablets USP, Valsartan HCTZ Tablets, USP and Valsartan Tablets USP were distributed nationwide to Aurobindo Pharma USA, Inc. wholesale, distributor, repackager and retail customers. Aurobindo Pharma USA, Inc. is notifying its distributors and customers by phone and in writing to immediately discontinue distribution of the specific lots being recalled and to notify their sub-accounts. Aurobindo Pharma USA, Inc. is arranging for return of all recalled products to Inmar/CLS Medturn. Instructions for returning recalled products are given in the recall letter.

Consumers with **medical questions regarding this recall or to report an adverse event** can contact Aurobindo Pharma USA, Inc. at:

- 1-866-850-2876 Option 2
- **pvg@aurobindousa.com (mailto:pvg@aurobindousa.com)**

Consumers should also contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Any general **questions regarding the return of this product** please contact Inmar\CLS-Medturn at 1-877-208-2407 or email **rxrecalls@inmar.com (mailto:rxrecalls@inmar.com)** (live calls received 9 am -5:00 pm Eastern Time).

Adverse reactions or quality problems associated with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program either by phone, on line, 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.

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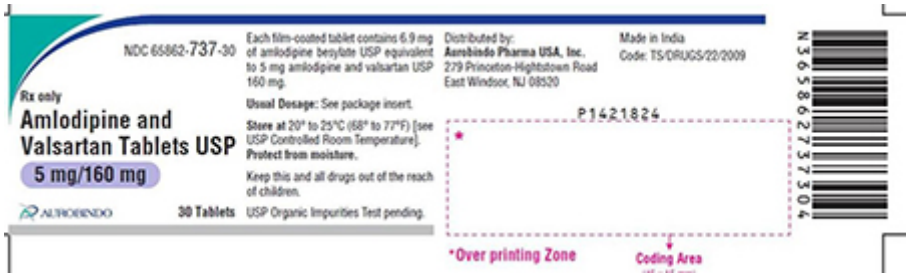
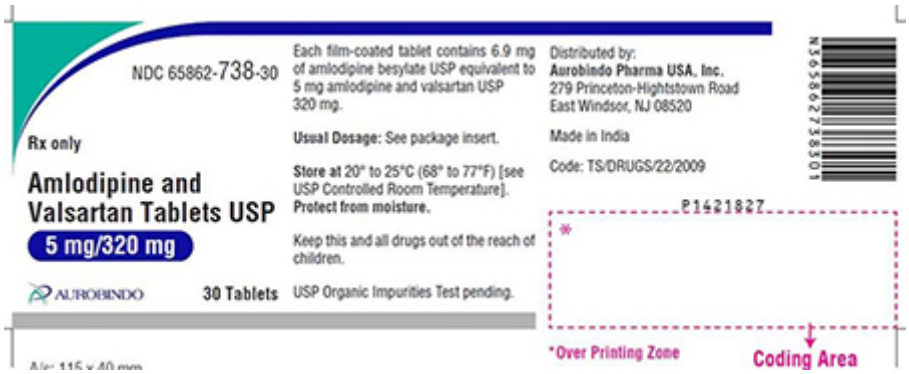
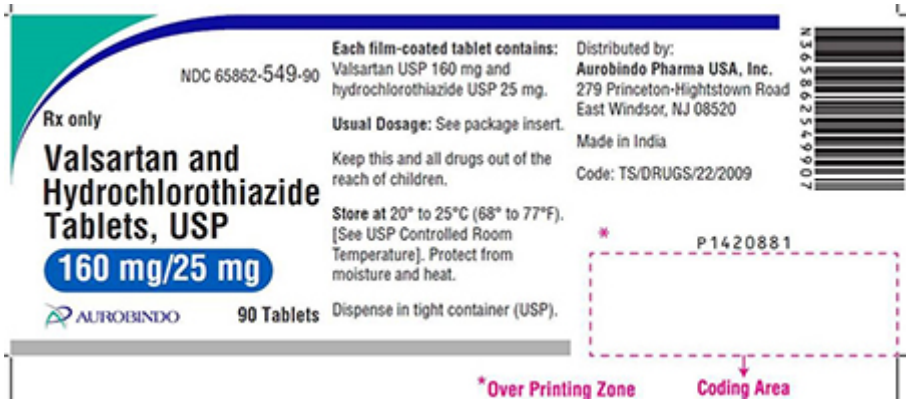
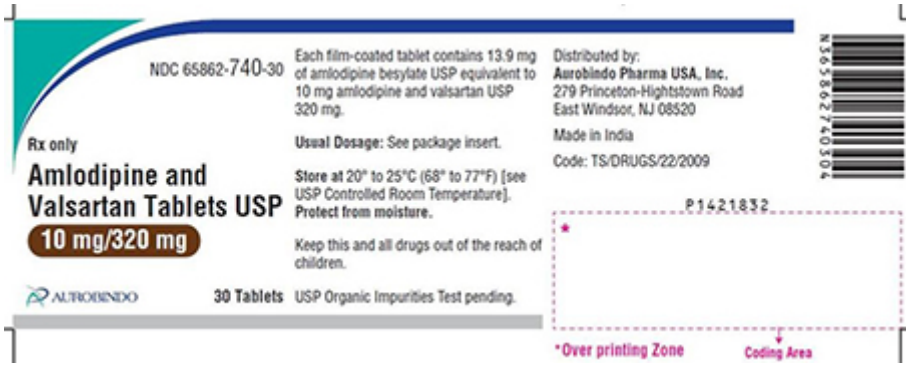
Product Photos






NDC 65862-549-90
Rx only
Valsartan and Hydrochlorothiazide Tablets, USP
160 mg/25 mg
AUROBINDO
90 Tablets
Each film-coated tablet contains: Valsartan USP 160 mg and hydrochlorothiazide USP 25 mg.
Usual Dosage: See package insert.
Keep this and all drugs 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.
Dispense in tight container (USP).
Distributed by:
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520
Made in India
Code: TS/DRUGS/22/2009
P1420881
*Over Printing Zone
Coding Area


NDC 65862-740-30
Rx only
Amlodipine and Valsartan Tablets USP
10 mg/320 mg
AUROBINDO
30 Tablets
Each film-coated tablet contains 13.9 mg of amlodipine besylate USP equivalent to 10 mg amlodipine and valsartan USP 320 mg.
Usual Dosage: See package insert.
Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture.
Keep this and all drugs out of the reach of children.
USP Organic Impurities Test pending.
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NDC 65862-550-90
Rx only
Valsartan and Hydrochlorothiazide Tablets, USP
320 mg/12.5 mg
AUROBINDO
90 Tablets
Each film-coated tablet contains: Valsartan USP 320 mg and hydrochlorothiazide USP 12.5 mg.
Usual Dosage: See package insert.
Keep this and all drugs 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.
Dispense in tight container (USP).
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P1420883
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Coding Area


NDC 65862-548-90
Rx only
Valsartan and Hydrochlorothiazide Tablets, USP
160 mg/12.5 mg
AUROBINDO
90 Tablets
Each film-coated tablet contains: Valsartan USP 160 mg and hydrochlorothiazide USP 12.5 mg.
Usual Dosage: See package insert.
Keep this and all drugs 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.
Dispense in tight container (USP).
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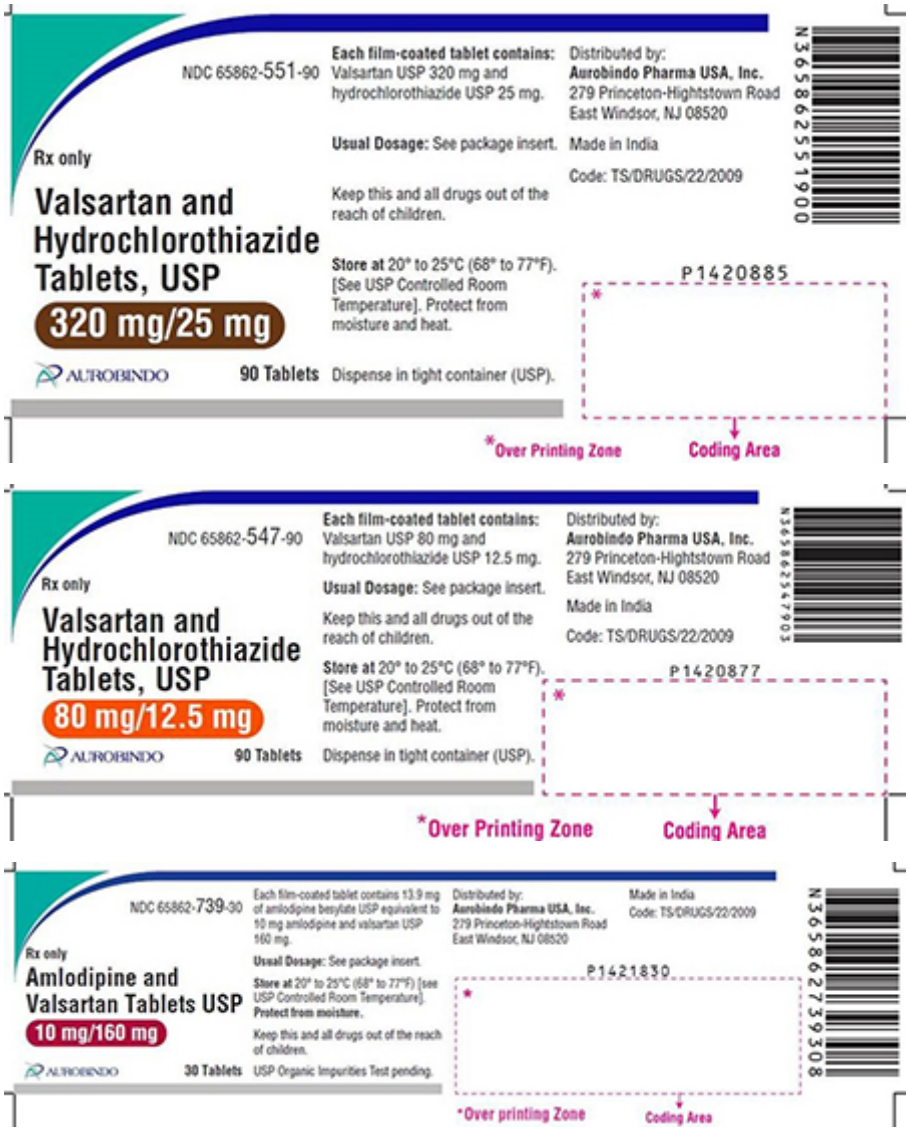

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