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.

American Health Packaging Issues Voluntary Nationwide Recall of Valsartan Tablets Due to the Detection of NDEA (N-Nitrosodiethylamine) Impurity

For Immediate Release

March 7, 2019

Contact

Consumers

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

Media

American Health Packaging
recalls@americanhealthpackaging.com (mailto:recalls@americanhealthpackaging.com)
(800) 707-4621

Announcement

View Product Photos

American Health Packaging is voluntarily recalling one lot of Valsartan Tablets, USP, 160 mg 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. This recall is being initiated in response to the recall by the manufacturer (Aurobindo Pharma USA, Inc.), which included the affected lot that was repackaged by American Health Packaging.

Valsartan Tablets USP are indicated to control high blood pressure and for the treatment of heart failure. Patients who prescribed 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.

Product was distributed Nationwide to Wholesalers for use in hospital settings. No reports of injury or adverse events to date.

Product Description	AHP Lot No.	Expiration Date
Valsartan Tablets USP 160 mg, 100 count Unit Dose Blisters Carton NDC#: 60687-139-01 (Individual Dose NDC: 60687-139-11)	179791	3/31/2020

American Health Packaging is notifying its distributors by recall letter sent March 6th, 2019 and to immediately discontinue distribution of the specific lots being recalled and to notify their sub- accounts. American Health Packaging is arranging for return of all recalled products to GENCO Pharmaceutical Services. Instructions for returning recalled products are given in the recall letter. Pharmacies that have received the affected lot should contact any patients who may have received the recall lots and have them call (877) 475-5864 to receive a return packet. Consumers should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication.

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)

Any general questions regarding the return of this product please contact GENCO Pharmaceutical Services at (877) 475-5864 or (live calls received 9 am -5:00 pm Central Time).

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

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.

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