AMERICAN HEALTH PACKAGING®
An AmerisourceBergen Company

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**URGENT PRODUCT RECALL**

March 6, 2019

Dear Valued Customer,

American Health Packaging, Inc. is initiating a voluntary drug recall to the **CONSUMER LEVEL** for **AHP Valsartan Tablets USP 160 mg, 100 count Unit Dose Blisters, Carton NDC#: 60687-139-01, (Individual Dose NDC: 60687-139-11),** for the lot listed below:

| Product Description | AHP Lot No. | Expiration Date | Ship Dates of Product |
|---|---|---|---|
| **Valsartan Tablets USP 160 mg, 100 count Unit Dose Blisters**<br>**Carton NDC#: 60687-139-01**<br>**(Individual Dose NDC: 60687-139-11)** | 179791 | 3/31/2020 | 08/23/2018 to 2/21/2019 |

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| **REASON** | This recall is being initiated in support of the recall by the manufacturer (Aurobindo Pharma USA, Inc.) dated February 25, 2019, which included lots that were repackaged by American Health Packaging.<br>Aurobindo stated that "This recall has been initiated 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." |
| **HEALTH HAZARD EVALUATION** | Valsartan Tablets USP are indicated to control high blood pressure and for the treatment of heart failure. Patients who are prescribed 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. Patients should contact their pharmacist or physician who can advise them about an alternative treatment prior to returning their medication. |

**ACTIONS REQUIRED**

1. **Distributors/Pharmacies** - Immediately examine your inventory, quarantine and discontinue distribution of these lots.
2. **Distributors** - Complete the enclosed Business Reply Card even if you do not have any product on hand.
3. **Distributors** - Please pass this Recall Notice on **ONLY** to pharmacies that received these product lots.
4. **Pharmacies** - If you have units of the affected products/lots in inventory, please contact GENCO Pharmaceutical Services at (877) 475-5864 to receive a recall return packet. If you have not received this product you do not need to request a return packet.
5. **Distributors/Pharmacies** - Return recalled product to GENCO as instructed in recall/return packet.
6. **Pharmacies** - Contact any patients who may have received the recall lots and have them call (877) 475-5864 to receive a return packet. Reimbursement will be provided by American Health Packaging for the amount of affected product returned. Only the affected lot will be reimbursed.
7. Carry out a physical count and record this data on the Business Reply Card and the Packing slip, which are included with this letter.
8. Return the recalled product and the Packing Slip using the prepaid FedEx shipping labels to:
   **GENCO Pharmaceutical Services a subsidiary of FedEx Supply Chain**
   **6101 North 64th Street**
   **Milwaukee, WI 53218**

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| **OTHER** | This Recall extends to the Consumer Level. No other lots, packages, or formulations are being recalled.<br>Please reorder stock immediately.<br>For questions about the recall process, call GENCO Pharmaceutical Services at (877) 475-5864.<br>This recall is being conducted with the knowledge of the Food and Drug Administration. We appreciate your immediate attention and cooperation and sincerely regret any inconvenience caused by this action. |

**To receive credit, the reply form and recalled product must be returned to GENCO by June 6th, 2018.**

Thank you for your support in complying with the requests in this letter. We apologize for the inconvenience that this incident may cause you or your customers.

Sincerely,

Becky A Mahon

Becky A Mahon
Regulatory Specialist
American Health Packaging