



Phone: (614) 492-8177
Toll Free Phone: (800) 707-4621

URGENT PRODUCT RECALL

February 01, 2024

Dear Valued Customer,

American Health Packaging, Inc. is initiating a voluntary drug recall to the **RETAIL LEVEL** for **AHP Hydralazine Hydrochloride Tablet USP, 10 mg, 100 UD; Carton NDC#: 68084-447-01, (Individual Dose NDC: 68084-447-11)**, for the lot listed below:

Product Description		AHP Lot No.	Expiration Date	Ship Dates of Product
AHP Hydralazine Hydrochloride Tablet USP, 10 mg, 100 UD Carton NDC#: 68084-447-01 (Individual Dose NDC: 68084-447-11)		1012275	02/28/2025	04/28/2023 to 08/29/2023
REASON	This recall is being initiated due to an Out of Specification (OOS) result in the repackaged product for Related Compounds (Impurities) at the 6-month time point.			
HEALTH HAZARD EVALUATION	HydrALAZINE hydrochloride, USP, is used for essential hypertension, alone or as an adjunct.			
ACTIONS REQUIRED				
<div>1. Distributors/Pharmacies - Immediately examine your inventory, quarantine and discontinue distribution of this lot.</div> <div>2. Distributors - <u>Complete the enclosed Business Reply Card even if you do not have any product on hand.</u></div> <div>3. Distributors - Please pass this Recall Notice on ONLY to pharmacies that received this product lot.</div> <div>4. Pharmacies - If you have units of the affected products/lot in inventory, please contact Sedgwick at (844) 593-4006 to receive a notification package with the Business Reply Card and return instructions.</div> <div>5. Business Reply Cards can be submitted by any of these methods. Fax: (844) 265-7413 Email: AHP8291@sedgwick.com Mail: 2670 Executive Dr., Ste. A, Indianapolis, IN 46241</div> <div>6. Distributors/Pharmacies - Return recalled product to Sedgwick as instructed in recall/return packet.</div> <div>7. Pharmacies - You do not need to contact any patients.</div>				
OTHER	This Recall extends to the Retail Level only. No other lots, packages, or formulations are being recalled. Please reorder stock immediately. For questions about the recall process, call Sedgwick at (844) 593-4006. 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 Sedgwick by April 30, 2024.

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 Mahon (Jan 30, 2024 14:21 EST)

Becky A Mahon
Sr. Regulatory Specialist
American Health Packaging