AMERICAN HEALTH PACKAGING®

- COLOR -

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

URGENT PRODUCT RECALL

October 16, 2025

Dear Valued Customer,

American Health Packaging is initiating a voluntary drug recall to the **RETAIL LEVEL** for **AHP Prazosin Hydrochloride Capsules, USP,**
1 mg, 100 Capsules (10x10); Carton NDC: 68084-996-01, (Individual Dose NDC: 68084-996-11)
2 mg, 100 Capsules (10x10); Carton NDC: 68084-997-01; (Individual Dose NDC: 68084-997-11)
5 mg, 20 Capsules (5x4); Carton NDC: 60687-572-32 (Individual Dose NDC: 60687-572-33) for the lots listed below:

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
AHP Prazosin Hydrochloride Capsules USP 1 mg, 100 Capsules (10x10) **Carton NDC#: 68084-996-01 (Individual Dose NDC: 68084-996-11)**	1023526	07/31/2026	05/01/2025 to 08/12/2025
	1023555	07/31/2026	06/03/2025 to 08/12/2025
AHP Prazosin Hydrochloride Capsules USP 2 mg, 100 Capsules (10x10) **Carton NDC#: 68084-997-01 (Individual Dose NDC: 68084-997-11)**	1020109	02/28/2026	10/07/2024 to 06/02/2025
	1024343	09/30/2026	06/16/2025 to 07/25/2025
	1025355	09/30/2026	08/20/2025 to 10/07/2025
AHP Prazosin Hydrochloride Capsules USP 5 mg, 20 Capsules (5x4) **Carton NDC#: 60687-572-32 (Individual Dose NDC: (60687-572-33)**	1016996	11/30/2025	03/06/2024 to 06/17/2024
	1018336	11/30/2025	06/14/2024 to 10/02/2024
	1021220	11/30/2025	12/02/2024 to 03/03/2025
	1022421	08/31/2026	03/10/2025 to 07/14/2025
	1025017	08/31/2026	07/18/2025 to 09/30/2025

REASON	This recall is being initiated in support of the recall by the manufacturer (Teva Pharmaceuticals USA LLC) dated October,07, 2025, which included lots that were repackaged by American Health Packaging. Teva stated they are initiating a voluntary recall of Prazosin Hydrochloride Capsules, USP (1 mg, 2 mg, 5 mg), due to test results for N-nitroso Prazosin impurity C that are above the Carcinogenic Potency Categorization Approach (CPCA) acceptable intake limit for the above specified lots.

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PRODUCT INDICATION	Prazosin hydrochloride capsules USP are indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from a wide variety of pharmacologic classes, including this drug.
HEALTH HAZARD EVALUATION	Teva stated "exposure to the product of concern could lead to severe adverse health consequences, but the likelihood of harm was assessed as remote. The overall risk of harm in the patient population is considered to be medium.

ACTIONS REQUIRED

1. **Distributors/Pharmacies** – Immediately examine your inventory, quarantine and discontinue distribution of this lot.
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 this product lot.
4. **Pharmacies** – If you have units of the affected products/lot in inventory, please contact Sedgwick at (888)-345-5359 to receive a notification package with the Business Reply Card and return instructions.
5. Business Reply Cards can be submitted by any of these methods.
   Fax: (888)-350-3629
   Email: ahp7299@sedgwick.com
   Mail: 2670 Executive Dr., Ste. A, Indianapolis, IN 46241
6. **Distributors/Pharmacies** – Return recalled product to Sedgwick as instructed in recall/return packet.
7. **Pharmacies** - You do not need to contact any patients.

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 (888)-345-5359. 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 Business Reply Card and recalled product must be returned to Sedgwick by December 31, 2025.
All reimbursements will be provided to the Wholesaler once recalled product is returned to and processed by Sedgwick.

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 Mahon (Oct 13, 2025 11:42:25 EDT)
Becky A Mahon
Sr. Manager, Regulatory Affairs and Stability
American Health Packaging