AMERICAN HEALTH PACKAGING®

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

URGENT PRODUCT RECALL

August 27, 2025

Dear Valued Customer,

American Health Packaging is initiating a voluntary drug recall to the **RETAIL LEVEL** for **AHP Chlorpromazine Hydrochloride Tablets, USP,**
25 mg, 100 Tablets (10x10); Carton NDC: 60687-430-01, (Individual Dose NDC: 60687-430-11)
25 mg, 50 Tablets (5x10); Carton NDC: 60687-430-65; (Individual Dose NDC: 60687-430-11)
50 mg, 100 Tablets (10x10); Carton NDC: 60687-441-01; (Individual Dose NDC: 60687-441-11)
100 mg, 100 Tablets (10x10); Carton NDC: 60687-452-01; (Individual Dose NDC: 60687-452-11)
200 mg, 100 Tablets (10x10); Carton NDC: 60687-463-01; (Individual Dose NDC: 60687-463-11) for the lots listed below:

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
AHP Chlorpromazine Hydrochloride Tablets, 25 mg, 100 Tablets (10x10) **Carton NDC#: 60687-430-01 (Individual Dose NDC: 60687-430-11)**	1020460	08/31/2026	10/18/2024 to 03/19/2025
	1022417	12/31/2026	03/19/2025 to 07/31/2025
AHP Chlorpromazine Hydrochloride Tablets, 25 mg, 50 Tablets (5x10) **Carton NDC#: 60687-430-65 (Individual Dose NDC: 60687-430-11)**	1020919	09/30/2026	10/17/2024 to 11/19/2024
	1021133	09/30/2026	11/06/2024 to 11/19/2024
	1021447	10/31/2026	12/02/2024 to 12/13/2024
	1021741	11/30/2026	01/09/2025 to 01/15/2025
	1022202	11/30/2026	01/24/2025 to 03/05/2025
	1022474	12/31/2026	03/06/2025 to 04/16/2025
AHP Chlorpromazine Hydrochloride Tablets, 50 mg, 100 Tablets (10x10) **Carton NDC#: 60687-441-01 (Individual Dose NDC: 60687-441-11)**	1022159	12/31/2026	02/24/2025 to 08/14/2025
	1023299	03/31/2027	05/27/2025 to 08/18/2025
	1024057	04/30/2027	07/09/2025 to 08/18/2025
AHP Chlorpromazine Hydrochloride Tablets, 100 mg, 100 Tablets (10x10) **Carton NDC#: 60687-452-01 (Individual Dose NDC: 60687-452-11)**	1021652	10/31/2026	12/18/2024 to 06/26/2025
	1022539	01/31/2027	03/14/2025 to 06/26/2025
	1023666	03/31/2027	06/26/2025 to 08/14/2025
AHP Chlorpromazine Hydrochloride Tablets, 200 mg, 100 Tablets (10x10) **Carton NDC#: 60687-463-01 (Individual Dose NDC: 60687-463-11)**	1021640	10/31/2026	01/15/2025 to 06/03/2025
	1022639	01/31/2027	05/05/2025 to 08/18/2025
REASON	This recall is being initiated in support of the recall by the manufacturer (Amneal Pharmaceuticals LLC) dated August 19, 2025, which included lots that were repackaged by American Health Packaging. Amneal stated they are initiating a voluntary recall of Chlorpromazine Hydrochloride Tablets, USP (25 mg, 50 mg, 100 mg, and 200 mg), which were "associated with a specific lot of auxiliary polyester coil, due to the detection of a micro-organism."		

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PRODUCT INDICATION	Chlorpromazine Hydrochloride Tablets are indicated for the management of manifestations of psychotic disorders. For the treatment of schizophrenia. To control nausea and vomiting. For relief of restlessness and apprehension before surgery. For acute intermittent porphyria. As an adjunct in the treatment of tetanus. To control the manifestations of the manic type of manic-depressive illness. For relief of intractable hiccups. For the treatment of severe behavioral problems in children (1 to 12 years of age) marked by combativeness and/or explosive hyperexcitable behavior (out of proportion to immediate provocations), and in the short-term treatment of hyperactive children who show excessive motor activity with accompanying conduct disorders consisting of some or all of the following symptoms: impulsivity, difficulty sustaining attention, aggressivity, mood lability and poor frustration tolerance.
HEALTH HAZARD EVALUATION	Amneal stated "No micro-organism was detected on any tablets from any of the retain sample bottles tested from the 30 batches being recalled. No market complaint or adverse event has been received for any of the recall specific batches for any microbial related issue. Out of an abundance of caution and commitment to quality Amneal is initiating a voluntary recall of the finished product batches that used this lot of polyester coil.

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)-266-7974 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)-203-3150
   Email: ahp3446@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)-266-7974. 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 November 30, 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 (Aug 25, 2025 15:51:15 EDT)
Becky A Mahon
Sr. Manager Regulatory Affairs and Stability
American Health Packaging

2025-08-27 Chlorpromazine HCl Tab Recall Letter (Amneal) - Retail

Final Audit Report 2025-08-25

Created:	2025-08-25
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"2025-08-27 Chlorpromazine HCl Tab Recall Letter (Amneal) - Retail" History

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