AMERICAN HEALTH PACKAGING®

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

URGENT PRODUCT RECALL

January 25, 2024

Dear Valued Customer,

American Health Packaging, Inc. is initiating a voluntary drug recall to the **RETAIL LEVEL** for **AHP Febuxostat Tablets, 40 mg, 30 UD; Carton NDC#: 60687-538-21, (Individual Dose NDC: 60687-538-11),** for the lot listed below:

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
AHP Febuxostat Tablets, 40 mg, 30 UD **Carton NDC#: 60687-538-21** **(Individual Dose NDC: 60687-538-11)**	1015033	06/30/2025	10/11/2023 to 01/22/2024

REASON	This recall is being initiated in support of the recall by the manufacturer (Sun Pharmaceutical Industries, Inc.) dated January 16, 2024, which included lots that were repackaged by American Health Packaging. Sun stated that "This recall has been initiated in response to microbial contamination in stagnant water found in the duct of the manufacturing equipment."
HEALTH HAZARD EVALUATION	Febuxostat tablets are xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in adult patients with gout who have an inadequate response to a maximally titrated dose of allopurinol, who are intolerant to allopurinol, or for whom treatment with allopurinol is not advisable.

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 (877) 787-0368 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: (877) 479-8072
   Email: AHP6283@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 Wholesale Level only. No other lots, packages, or formulations are being recalled. Please reorder stock immediately. For questions about the recall process, call Sedgwick at (877) 787-0368. 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 30th, 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 A Mahon
Becky Mahon (Jan 23, 2024 12:40 EST)

Becky A Mahon
Regulatory Specialist, American Health Packaging