AMERICAN HEALTH PACKAGING®
An AmerisourceBergen Company

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URGENT PRODUCT RECALL

February 7, 2020

Dear Valued Customer,

American Health Packaging, Inc. is initiating a voluntary drug recall to the **RETAIL LEVEL** for **AHP Desmopressin Acetate Tablets 30 count Unit Dose Blisters, 0.1 mg – Carton NDC#: 68084-606-21, (Individual Dose NDC: 68084-606-11) and 0.2 mg – Carton NDC#: 68084-604-21, (Individual Dose NDC: 68084-604-11),** for the lots listed below:

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
AHP Desmopressin Acetate Tablets 0.1 mg 30 count Unit Dose Blisters **Carton NDC#: 68084-606-21** **(Individual Dose NDC: 68084-606-11)**	181109	04/30/2020	12/17/2018 to 04/08/2019
AHP Desmopressin Acetate Tablets 0.2 mg 30 count Unit Dose Blisters	180510	03/31/2020	11/01/2018 to 05/29/2019
Carton NDC#: 68084-604-21 **(Individual Dose NDC: 68084-604-11)**	181912	04/30/2020	02/15/2019 to 05/20/2019

REASON	This recall is being initiated in support of the recall by the manufacturer (Teva Pharmaceuticals USA, Inc.) dated January 28, 2020, which included lots that were repackaged by American Health Packaging. Teva stated that "This recall is being initiated due to the possibility of desiccant count discrepancy in the above lots. As per the product packaging specification, each product bottle is packaged with one (1) 2 Gram Sorb-it Canister desiccant. However, there is a possibility that the above lots may contain no desiccant."
HEALTH HAZARD EVALUATION	Based on the available information, the suspected risk of product bottle with no desiccant is reduced efficacy or lack of efficacy. However, patients treated with Desmopressin are subject to periodic clinical monitoring by their treating physician in order to evaluate the therapeutic response of the drug. Further, individual dose adjustment based on severity of symptoms and patient's response minimize the possible incident of reduced drug efficacy.

ACTIONS REQUIRED

1. **Distributors/Pharmacies** - Immediately examine your inventory, quarantine and discontinue distribution of this lot.
2. **Distributors** - Complete the enclosed Business Reply Form 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 Inmar Pharmaceuticals Services at 800-967-5952 (option 1) to receive a Business Recall Response form or acquire it from clsnetlink.com.
5. Business Recall Response Form can be submitted by any of these methods.
   Fax: 817-868-5362
   Email: rxrecalls@inmar.com
   Address: Inmar, Attn: Recall Coordinator - 635 Vine St, Winston Salem, NC 27101
6. **Distributors/Pharmacies** - Return recalled product to Inmar Pharmaceuticals Services 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 Inmar Pharmaceuticals Services at 800-967-5952. 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 Inmar by May 30th, 2020.

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
Regulatory Specialist, American Health Packaging