



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

**URGENT PRODUCT RECALL**

August 9, 2019

Dear Valued Customer,

American Health Packaging, Inc. is initiating a voluntary drug recall to the **RETAIL LEVEL** for **AHP Carbamazepine Extended-Release Tablets, USP 400 mg, 30 count Unit Dose Blisters, Carton NDC#: 68084-562-21, (Individual Dose NDC: 68084-562-11)**, for the lot listed below:

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
<b>AHP Carbamazepine Extended-Release Tablets, USP 400 mg, 30 count Unit Dose Blisters</b> <b>Carton NDC#: 68084-562-21</b> <b>(Individual Dose NDC: 68084-562-11)</b>	181677	11/30/2020	1/18/2019 to 5/2/2019
<b>REASON</b>	This recall is being initiated due to dissolution failure at time zero of the repackaged lot. Drug release results for were below specification at time zero.		
<b>HEALTH HAZARD EVALUATION</b>	Carbamazepine USP is an anticonvulsant and specific analgesic for trigeminal neuralgia.		
<b>ACTIONS REQUIRED</b>			
<ol style="list-style-type: none"> <li><b>Distributors/Pharmacies</b> - Immediately examine your inventory, quarantine and discontinue distribution of these lots.</li> <li><b>Distributors</b> - <u>Complete the enclosed Business Reply Form even if you do not have any product on hand.</u></li> <li><b>Distributors</b> - Please pass this Recall Notice on <b>ONLY</b> to pharmacies that received these product lots.</li> <li><b>Pharmacies</b> - If you have units of the affected products/lots in inventory, please contact Inmar Pharmaceuticals Services at 800-967-5952 (option 1) to receive a Business Recall Response form or acquire it from <a href="http://clsnetlink.com">clsnetlink.com</a>.</li> <li>Business Recall Response Form can be submitted by any of these methods. <b>Fax:</b> 817-868-5362 <b>Email:</b> <a href="mailto:rxrecalls@inmar.com">rxrecalls@inmar.com</a> <b>Address:</b> Inmar, Attn: Recall Coordinator - 635 Vine St, Winston Salem, NC 27101</li> <li><b>Distributors/Pharmacies</b> - Return recalled product to Inmar Pharmaceuticals Services as instructed in recall/return packet.</li> <li><b>Pharmacies</b> - You do not need to contact any patients.</li> </ol>			
<b>OTHER</b>	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 November 9<sup>th</sup>, 2019.**

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