

**URGENT PRODUCT RECALL**

January 7, 2021

Dear Valued Customer,

American Health Packaging, Inc. is initiating a voluntary drug recall to the **RETAIL LEVEL** for **AHP (Twice-a-day Dosage) Nitrofurantoin Capsules USP (Monohydrate/Macrocrystals), 100 mg, 100UD; Carton NDC#:68084- 446-01, (Individual Dose NDC: 68084- 446-11)**, for the lot listed below:

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
<b>AHP (Twice-a-day Dosage) Nitrofurantoin Capsules USP (Monohydrate/Macrocrystals), 100 mg, 100UD</b> <b>Carton NDC#: 68084- 446-01</b> <b>(Individual Dose NDC: 68084- 446-11)</b>	193757	1/31/2022	09/01/2020 to 11/23/2020
<b>REASON</b>	This recall is being initiated due to dissolution failure at 0-time of the repackaged lot. Drug release results for were above specification at the 0-time.		
<b>HEALTH HAZARD EVALUATION</b>	Nitrofurantoin capsules USP (monohydrate/macrocrystals) are indicated only for the treatment of acute uncomplicated urinary tract infections (acute cystitis) caused by susceptible strains of Escherichia coli or Staphylococcus saprophyticus.		
<b>ACTIONS REQUIRED</b>			
<ol style="list-style-type: none"> <li><b>Distributors/Pharmacies</b> - Immediately examine your inventory, quarantine and discontinue distribution of this lot.</li> <li><b>Distributors</b> - Complete the enclosed Business Reply Card even if you do not have any product on hand.</li> <li><b>Distributors</b> - Please pass this Recall Notice on <b>ONLY</b> to pharmacies that received this product lot.</li> <li><b>Pharmacies</b> - If you have units of the affected products/lot in inventory, please contact Stericycle at 888-671-8859 to receive a notification package with the Business Reply Card and return instructions.</li> <li>Business Reply Cards can be submitted by any of these methods.  <b>Fax:</b> 888-345-0476  <b>Email:</b> <a href="mailto:americanhealthpackaging6758@stericycle.com">americanhealthpackaging6758@stericycle.com</a>  <b>Mail:</b> 6026 Lakeside Blvd. Indianapolis, IN 46278</li> <li><b>Distributors/Pharmacies</b> - Return recalled product to Stericycle 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 Stericycle at 888-671-8859. 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 Stericycle by March 31, 2021.**

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 Mahon (Jan 6, 2021 10:06 EST)

Becky A Mahon  
Regulatory Specialist, American Health Packaging