



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

**URGENT PRODUCT RECALL**

May 01, 2026

Dear Valued Customer,

American Health Packaging, Inc. is initiating a voluntary drug recall to the **RETAIL LEVEL** for **AHP Primidone Tablets USP**,

**50 mg, 100 UD; Carton NDC: 68084-202-01, (Individual Dose NDC: 68084-202-11),**  
**250 mg, 100 UD; Carton NDC: 68084-203-01, (Individual Dose NDC: 68084-203-11),**  
for the lots listed below:

Product Description	AHP Lot No.	Expiration Date	Ship Dates of Product
<b>AHP Primidone Tablets USP</b> <b>50 mg, 100 Tablets (10x10)</b>  <b>Carton NDC: 68084-202-01</b> <b>(Individual Dose NDC: 68084-202-11)</b>	1028739	12/31/2027	02/17/2026 to 03/24/2026
	1025622	06/30/2027	09/24/2025 to 11/10/2025
<b>AHP Primidone Tablets USP</b> <b>250 mg, 100 Tablets (10x10)</b>  <b>Carton NDC: 68084-203-01</b> <b>(Individual Dose NDC: 68084-203-11)</b>	1027583	09/30/2027	01/14/2026 to 03/23/2026
<b>REASON</b>	This recall is being initiated in support of the recall by the manufacturer (Lannett Company, Inc) dated April,23, 2026, which included lots that were repackaged by American Health Packaging. This recall is being carried out due to a potential for cross-contamination with Acemetacin API due to an issue at the API manufacturer.		
<b>PRODUCT INDICATION</b>	Primidone, used alone or concomitantly with other anticonvulsants, is indicated in the control of grand mal, psychomotor, and focal epileptic seizures. It may control grand mal seizures refractory to other anticonvulsant therapy.		
<b>HEALTH HAZARD EVALUATION</b>	A Health Hazard Evaluation was conducted to assess the risk of Primidone tablets contaminated with trace amounts of Acemetacin (an NSAID). Testing confirmed Acemetacin levels were below the limits of quantification, and the worst-case daily exposure ( $\leq 1.48$ mg/day) is far below therapeutic doses (60–180 mg/day). The overall risk to patients is low, with no clinically relevant adverse effects expected.		
<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> – <u>Complete the enclosed Business Reply Card 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 this product lot.</li> <li><b>Pharmacies</b> – If you have units of the affected products/lot in inventory, please contact Sedgwick at (877)-870-7363 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> (877)-479-8090.  <b>Email:</b> <a href="mailto:ahp8744@sedgwick.com">ahp8744@sedgwick.com</a>  <b>Mail:</b> 2670 Executive Dr., Ste. A, Indianapolis, IN 46241</li> <li><b>Distributors/Pharmacies</b> – Return recalled product to Sedgwick 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 Sedgwick at (877)-870-7363.  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 July 31, 2026.**

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 (Apr 30, 2026 10:34:37 EDT)

Becky A Mahon  
Sr. Manager, Regulatory Affairs and Stability  
American Health Packaging



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

NDC 68084-202-01

# Primidone

Tablets, USP

## 50 mg

100 Tablets (10 x 10) Rx Only

(01) 0 03 68084 202 01 8

**PHARMACIST:** Dispense with Medication Guide to each patient.

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NDC 68084-202-01

# Primidone

Tablets, USP

## 50 mg

100 Tablets (10 x 10) Rx Only

**Each Tablet Contains:**  
Primidone, USP.....50 mg

**Usual Dosage:** See full prescribing information.

**Store** at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

**FOR YOUR PROTECTION:** Do not use if blister is torn or broken.

The drug product contained in this package is from NDC # 0527-1301, Lannett Company, Inc.

Distributed by: American Health Packaging, Columbus, Ohio 43217

Scan for current Medication Guide and Prescribing Information

084340  
0220201/0924

Primidone  
Tablet, USP  
50 mg

(01) 003 68084 202 11 7  
American Health Packaging, Columbus, Ohio 43217

Primidone  
Tablet, USP  
50 mg

(01) 003 68084 202 11 7  
American Health Packaging, Columbus, Ohio 43217

Primidone  
Tablet, USP  
50 mg

(01) 003 68084 202 11 7  
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(01) 003 68084 202 11 7  
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American Health Packaging, Columbus, Ohio 43217

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American Health Packaging, Columbus, Ohio 43217

Primidone  
Tablet, USP  
50 mg

(01) 003 68084 202 11 7  
American Health Packaging, Columbus, Ohio 43217

NDC 68084-203-01

# Primidone

Tablets, USP

## 250 mg

100 Tablets (10 x 10) Rx Only

(01) 0 03 68084 203 01 5

**PHARMACIST:** Dispense with Medication Guide to each patient.

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NDC 68084-203-01

# Primidone

Tablets, USP

## 250 mg

100 Tablets (10 x 10) Rx Only

**Each Tablet Contains:**  
Primidone, USP.....250 mg

**Usual Dosage:** See full prescribing information.

**Store** at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].

**FOR YOUR PROTECTION:** Do not use if blister is torn or broken.

The drug product contained in this package is from NDC # 0527-1231, Lannett Company, Inc.

Distributed by: American Health Packaging, Columbus, Ohio 43217

Scan for current Medication Guide and Prescribing Information

085014  
0220301/0924

Primidone  
Tablet, USP  
250 mg

(01) 003 68084 203 11 4  
American Health Packaging, Columbus, Ohio 43217

Primidone  
Tablet, USP  
250 mg

(01) 003 68084 203 11 4  
American Health Packaging, Columbus, Ohio 43217

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Tablet, USP  
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Primidone  
Tablet, USP  
250 mg

(01) 003 68084 203 11 4  
American Health Packaging, Columbus, Ohio 43217





# 2026-04-27 Primidone Tablets USP Recall Letter (Lannett) - Retail

Final Audit Report

2026-04-30

Created:	2026-04-30
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## "2026-04-27 Primidone Tablets USP Recall Letter (Lannett) - Retail" History

-  Document created by Damini Patel (DAMINI.PATEL@americanhealthpackaging.com)  
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-  Document e-signed by Becky Mahon (BMahon@americanhealthpackaging.com)  
Signature Date: 2026-04-30 - 2:34:37 PM GMT - Time Source: server
-  Agreement completed.  
2026-04-30 - 2:34:37 PM GMT