URGENT: DRUG RECALL

Hindy Schiff
Vice President Regulatory Affairs and Compliance
Ascend Laboratories, LLC
135 US Highway 202-206, Suite 15
Bedminster, NJ, 07921

August 12, 2025

Dear Customer:

This is to inform you of a product recall involving Amlodipine and Olmesartan Medoxomil Tablets, 5mg/40mg. Please reference lot-specific information included below.

	Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Initial Distribution Date	Quantity Distributed (in bottles)
1	Amlodipine and Olmesartan Medoxomil Tablets	23121560	5 mg/ 40 mg	April 30, 2026	30 tablets/ bottle	67877-501-30	August 14, 2023	8,568

See enclosed product labels for ease in identifying the product at the RETAIL level.

An out-of-specification (OOS) result was observed during dissolution testing for Olmesartan content of reserve samples for batch number 23121560. For both the S1 and S3 stage criteria.

Amlodipine and Olmesartan Medoxomil is a combination drug. Amlodipine besylate is a calcium channel blocker and Olmesartan Medoxomil is an angiotensin II receptor blocker; in combination, this prescription drug is indicated for treatment of hypertension to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events. Delayed dissolution of the product may delay the onset of the drug's pharmacological action.

Our firm began shipping this product on August 14, 2023. Immediately examine your inventory and quarantine product subject to recall for the lot number specified in the table above.

Please perform the following activities:

a. Immediately examine your inventory and quarantine product subject to recall for the lot numbers specified in the table above. Please follow the directions in the attached recall stock response to return the affected product.
b. Promptly complete the attached recall stock response form even if you have no product to return.
c. The completed Recall Response Form can be submitted by any of the following methods:

Fax: 817-868-5362 or E-mail: rxrecalls@inmar.com

This recall is being carried out to the RETAIL level. Your assistance is appreciated and necessary to prevent consumer harm.

Your assistance is appreciated and necessary in this voluntary recall. If you have any questions related to customer service, please contact product inquiries—available 24 hours a day, 7 days a

week—at 877-272-7901. If you have any questions about the return of the product, please contact Inmar toll free at 855-714-4351—available 9:00 AM to 5:00 PM ET Monday through Friday.

This recall is being conducted with the knowledge of the Food and Drug Administration.

Sincerely,

Hindy Schiff

Vice President, Regulatory Affairs and Compliance

RECALL STOCK RESPONSE FORM

Recall: Amlodipine and Olmesartan Medoxomil Tablets, 5 mg/40 mg

Lot Number 23121560

Customer Name: _____ DEA #:_____

***Please note that DEA # is required. If it is not provided, the processing of your form will be delayed. ***

Address:_____

City:_____ State:_____ Zip Code:_____

Contact Name (please print): _____Telephone #:_____

Contact Signature: _____ Date:_____

Wholesaler Information if not directly purchased from Ascend:

Wholesaler Name: _____Wholesaler DEA#:_____

Wholesaler City:_____ Wholesaler State:_____ Wholesaler Zip: _____

Please check and fill out each section accordingly.

- ☐ I have read and understand the recall instructions provided in the Recall Letter.
- ☐ I have checked my stock for the quarantined inventory indicated in the table below.

	Product Name	Lot Number	Strength	Expiration Date	Pack Size	NDC	Quantity on Hand (in bottles)
1	Amlodipine and Olmesartan Medoxomil Tablets	23121560	5 mg/ 40 mg	April 30, 2026	30 tablets/ bottle	67877-501-30	
Total Product							

- ☐ Indicate disposition of recall product:
  - Returned/Held for Return (Yes / No)
    - Quantity: _____
    - Date: _____
    - Method: _____

  OR

  - No recall product on hand (Yes / No)

- ☐ I have identified and notified my customers that this product was shipped/received or may have been shipped by:
  - Date: _____
  - Method of Notification: _____

Were there any adverse events associated with the recalled product?

- ☐ Yes
- ☐ No

If yes, please explain: _____

If you have any questions regarding this form or product return, please contact Inmar at 1-855-714-4351. Office Hours: 9:00 AM to 5:00 PM EST Monday through Friday.

Please return this form by fax to 1-817-868-5362 or E-mail rxrecalls@inmar.com.

After receipt of this response form, a return kit will be provided for affected product return to:

Inmar Rx Solutions

3845 Grand Lakes Way

Grand Prairie, TX, 75050

Inmar Recall Event ID: RCL163-2025