



URGENT: DRUG RECALL

Dear Customer:

October 6, 2026

This is to inform you of a product recall involving Amlodipine and Olmesartan Medoxomil Tablets, 10 mg/40 mg. 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 10mg/40mg	25120696	10mg/40mg	December 31, 2026	30 tablets/bottle	67877-502-30	June 4, 2025	11,424 bottles

See enclosed product labels for ease in identifying the product.

During testing of the reserve sample for Amlodipine and Olmesartan Medoxomil Tablets 10 mg/40 mg (Batch No. 25120696), an out-of-specification (OOS) result was identified for the dissolution assay of the Olmesartan Medoxomil component. The dissolution results for Amlodipine were within the established acceptance criteria and met the applicable specification requirements.

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 June 4, 2025. Immediately examine your inventory and quarantine product subject to recall for the lot number specified in the table above.

Please perform the following activities:

- 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.
- Promptly complete the attached recall stock response form even if you have no product to return.
- The completed Recall Response Form can be submitted by any of the following methods:

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

- If you may have further distributed this product, please identify your customers and notify them at once of this product recall to the retail level. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

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 1-877-378-1076—available 9:00 AM to 5:00 PM ET Monday through Friday (excluding holidays).



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

Sincerely,

Sudhir Kaushal Digitally signed by Sudhir Kaushal
Date: 2026.10.05 09:14:29 -04'00'

Sudhir Kaushal

Sr. Director, Regulatory Affairs and Compliance

RECALL STOCK RESPONSE FORM

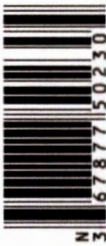
Annexure-I to Product Recall initiation form

Product Images:

Batch No.	Label Part I	Label Part II	Label part III
25120696			

Annexure-I to Product Recall initiation form

Plain Specimen Label:

Each tablet contains 13.9 mg of amlodipine besylate, USP, equivalent to 10 mg of amlodipine and 40 mg of olmesartan medoxomil, USP. Dosage and use: See package insert. Store at 25°C (77°F); excursions permitted between 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature]. Manufactured by: ALKEM Alkem Laboratories Ltd., INDIA. Distributed by: Ascend Laboratories, LLC Parsippany, NJ 07054	NDC 67877-502-30 Amlodipine and Olmesartan Medoxomil Tablets 10mg/40mg Rx Only 30 Tablets ASCEND Laboratories, LLC	 N 3 67877 50230 4	Unvarnished area 45 x 20 mm (LXH) Rest label should be with UV Varnish 
Code No.: HP/Drugs/MNB/05/105		PL9894-01	

Prepared by:	Checked by:



Recall: Amlodipine and Olmesartan Medoxomil Tablets 10mg/40mg

Lot Number: 25120696

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 10mg/40mg	25120696	10mg/40mg	December 31, 2026	30 tablets/bottle	67877-502-30	
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 1-877-378-1076.
Office Hours: 9:00 AM to 5:00 PM EST Monday through Friday (excluding holidays).

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: RCL297-26