URGENT DRUG RECALL
Matzim® LA Extended-Release Tablets
July 21, 2022

Teva Pharmaceuticals USA, Inc.

Matzim® LA (Diltiazem Hydrochloride) Extended-Release Tablets					
NDC	**Lot #**	**Exp. Date**	**Strength**	**Size**	**Dates Distributed**
52544-691-30	1411593A	09/2022	180 mg	30 Tablets/bottle	12/02/2020 - 12/30/2020
52544-692-30	1411596A	09/2022	240 mg	30 Tablets/bottle	12/04/2020 - 01/06/2021

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (Teva USA) is initiating a voluntary recall of the above drug product lots to the Retail Level. Please take the following actions given below. The subject product lots are packaged and distributed under label of Actavis Pharma Inc.

This recall is being initiated because of a recent stability result for dissolution testing of lot 1411596A, which is below specification limits and lot 1411593A is trending towards this out of specification at its expiration.

The main safety concern that may arise for the concerned product is decreased effectiveness and/or ineffectiveness to exert its antihypertensive and antianginal effects. Exposure to the product of concern may result moderate adverse events and the likelihood of occurrence is considered possible. The manifestations of lack of effect, might theoretically consist of inadequate control of the blood pressure, severe headaches or fatigue, dizziness, nervousness, sweating, chest pain, irregular heartbeats, tremor, manifestations of cardiac deterioration, poorly controlled angina pectoris or manifestation of arrhythmias.

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

ACTIONS: Please *promptly* perform the following actions that are necessary for this recall:

- Examine your inventory for the above drug product NDCs and Lot numbers.
- Quarantine and cease distribution of the product lots indicated for this recall.
- Promptly complete the enclosed Recall Stock Response Form (SRF), *even if you have **no** product to return*.
- Promptly return your completed SRF by any one of these means to Inmar, Attn: Recall Coordinator:

  MAIL: Inmar, 635 Vine Street, Winston Salem, NC 27101
  EMAIL: **rxrecalls@inmar.com**
  FAX: 817-868-5362.

- **If you have further distributed product lot affected by this recall, please perform a SUB-RECALL to your accounts using this Recall Notification and Stock Response Form as a basis of your recall notification.**

After receipt of your completed SRF, if you have recorded product to return, Inmar will send labels for Return Goods Authorization (RGA) and the return shipping labels. Appropriate credit for your product returns, plus handling and shipping expenses, will be issued after receipt of said product and your RGA. All recalled product returned without a RGA may delay the issuance of a credit. Products returned that are not the subject of the recall will not be credited and will be destroyed.

CONTACT INFORMATION
Product Returns and Stock Response Forms: Contact Inmar at: 855-916-4325 (Hours of Operation: 9 am to 5 pm Eastern Time) or acquire forms from clsnetlink.com.
Medical-related Questions or to report an Adverse Event: Contact Medical Information at: 888-838-2872, option 3, then, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week Or Email druginfo@tevapharm.com
Product Quality Complaint-related Questions: Contact Quality Assurance Services: 888-838-2872, option 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 3 then, option 2 Live calls received: M - F, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
FDA contact information for reporting adverse events/quality complaints: Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088

Sincerely,

Regulatory Compliance, Teva Pharmaceuticals USA, Inc.

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STOCK RESPONSE FORM

Enter the information of the recalled product to be returned in the table below. If additional space is needed, please make copies of this form.

Please fill out completely **Date:** _____

DIRECT CUSTOMERS ONLY: Does this response include **all** your DC locations? ☐ YES ☐ NO	
Customer/Store Name:	
*DEA #: ***DEA # is required; in order to process your form.***	*Debit Memo #
Address:	City/State/Zip
Contact Name (please print):	Telephone #:

I have checked my stock and:

_____ I **do not** have stock of the recalled item(s) **OR** _____ I **do** have stock of the recalled item(s) listed above.

Matzim® LA (Diltiazem Hydrochloride) Extended-Release Tablets					
NDC	**Lot #**	**Exp. Date**	**Strength**	**Size**	**Quantity to Return (Count Partial Bottles as 1)**
52544-691-30	1411593A	09/2022	180 mg	30 Tablets/bottle	
52544-692-30	1411596A	09/2022	240 mg	30 Tablets/bottle	

Please send me _____ shipping box labels

NON DIRECT CUSTOMERS ONLY: Please complete the following:	
City / State	DEA #: ***DEA # is required; in order to process your form.***
Purchased From (Wholesaler name):	

Promptly return your completed SRF by any one of these means to Inmar, Attn: Recall Coordinator
MAIL: Inmar, 635 Vine Street, Winston Salem, NC 27101
EMAIL: rxrecalls@inmar.com
FAX: 817-868-5362

Inmar/MedTurn Use Only:				
Scan	Labels	Store	Kit	D.B