Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – CONSUMER LEVEL - INITIATED 11/26/18

Amlodipine, Valsartan, and Hydrochlorothiazide Tablets

NDC 0093-7807-56 & 0093-7807-98 5 mg/160 mg/12.5 mg
NDC 0093-7810-56 & 0093-7810-98 10 mg/160 mg/12.5 mg
NDC 0093-7038-56 & 0093-7038-98 10 mg/160 mg/25 mg
NDC 0093-7809-56 & 0093-7809-98 10 mg/320 mg/25 mg
30 and 90 Count Bottles

RECALLED BY:
Teva Pharmaceuticals USA, Inc.
North Wales, PA 19454

All Lots Within Expiry – See Attached Stock Response Form

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling to the **CONSUMER LEVEL *All Lots Within Expiry*** of the above listed **Amlodipine, Valsartan, and Hydrochlorothiazide Tablets** that were distributed under the **Teva Pharmaceuticals label.** These lots are being recalled due to an impurity, N-nitrosodiethylamine (NDEA), which is above specification limits in the Valsartan Active Pharmaceutical Ingredient (API) that was manufactured by Mylan Laboratories Limited in India.

Based on the available information, long term use of the product containing high levels of the impurity cannot be ruled out as potentially being linked to risk of developing cancer in a few patients. However, all reported adverse event cases received thus far are lacking critical information limiting any application of a proper causality analysis. Patients should contact their pharmacist or physician for advice on alternative treatment prior to returning their medication. Patients who are on Amlodipine, Valsartan, and Hydrochlorothiazide combination tablets are advised to continue taking their medication. The risk of harm to a patient's health may be higher if the treatment is stopped immediately without any comparable alternative treatment.

Wholesalers / Distributors / Retailers - Please perform the following activities:

- Immediately examine your inventory for the specified lots of **Amlodipine, Valsartan, and Hydrochlorothiazide Tablets.**
- Our records indicate we shipped this product between December 7, 2016 and March 2, 2018.
- Immediately discontinue distribution of the specific lot being recalled.
- **Wholesalers/Distributors/Retailers, if you have further distributed the specific lots, please perform a SUB-RECALL to your RETAIL accounts using this Recall Notification and Stock Response Form.**
- Even if you have **no** product to return, promptly complete the attached recall stock response form (SRF) and return by mail, email, or FAX to Inmar, Attn: Recall Coordinator,
  Inmar, 635 Vine Street, Winston Salem, NC 27101
  Email address: **rxrecalls@inmar.com.**
  FAX: 817-868-5362.

Inmar will send a Return Goods Authorization label and shipping label, if requested on your SRF. Appropriate credit for product returns, plus handling and shipping expenses, will be issued upon receipt of said product with the Return Goods Authorization form. All recalled product returned without a Return Goods Authorization label 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 AND CREDIT
Product Returns: Contact Inmar at: 877-297-8404. (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response forms Contact Inmar at: 877-297-8404 or acquire it from clsnetlink.com.
Customer Service-related Questions: Contact Teva Customer Service: 800-545-8800 (Hours of Operation: Live calls received: Monday-Friday, 8:30AM-5:00PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week).
Medical-related Questions or to report an Adverse Event: Contact Medical Information at: 888-838-2872, option 3, then, option 4 Live calls received: Monday-Friday, 9:00AM-5:00PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
Product Quality Complaint-related Questions: Contact Quality Assurance Services: 888-838-2872, option 3, then, option 3 (Hours of Operation: Live calls received: Monday-Friday, 9:00AM-5:00PM 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 - Page 1 of 2 (Please return all pages)

Please fill out completely **Date:** _____

DIRECT CUSTOMERS ONLY: Does this response include **all** DC locations? ☐ YES ☐ NO

Customer/Store Name: _____ DEA #: _____
**DEA # is required; if not provided the processing of your form will be delayed*

Address: _____

City: _____ State: _____ Zip: _____

Contact Name (please print): _____ Telephone #: _____

Lot #	Exp. Date	Strength	Bottle Size	NDC	Quantity to Return (count partial as 1)
18X010	02/2019	5 mg/160 mg/12.5 mg	30 count	0093-7807-56	
18X010	02/2019	5 mg/160 mg/12.5 mg	90 count	0093-7807-98	
18X011	02/2019	5 mg/160 mg/12.5 mg	30 count	0093-7807-56	
20X006	11/2018	10 mg/160 mg/12.5 mg	30 count	0093-7810-56	
20X006	11/2018	10 mg/160 mg/12.5 mg	90 count	0093-7810-98	
21X006	11/2018	10 mg/160 mg/25 mg	30 count	0093-7038-56	
21X006	11/2018	10 mg/160 mg/25 mg	90 count	0093-7038-98	
21X007	02/2019	10 mg/160 mg/25 mg	30 count	0093-7038-56	
22X045	02/2019	10 mg/320 mg/25 mg	30 count	0093-7809-56	
22X045	02/2019	10 mg/320 mg/25 mg	90 count	0093-7809-98	
22X046	02/2019	10 mg/320 mg/25 mg	30 count	0093-7809-56	
22X047	02/2019	10 mg/320 mg/25 mg	30 count	0093-7809-56	

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STOCK RESPONSE FORM - Page 2 of 2 (Please return all pages)

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.

Please send me _____ shipping box labels

NON DIRECT CUSTOMERS ONLY: Please complete the following:

Purchased From (Wholesaler name): _____ DEA #: _____

City: _____ State: _____

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Please FAX this form to: 817-868-5362 or E-mail at: rxrecalls@inmar.com or mail to:
Inmar, Attn: Recall Coordinator, Inmar, 635 Vine Street, Winston Salem, NC 27101.

Inmar/MedTurn Use Only:

Scan	Labels	Store	Kit	D.B