Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 4/1/14

Lansoprazole DR Capsules USP 30mg, Amoxicillin Capsules USP 500mg, & Clarithromycin Tablets USP 500mg (Triple Therapy)

NDC# 0093-8055-14 (carton of 14 x 8 cards)/0093-8055-78 (individual cards)

MANUFACTURED BY:
Lansoprazole DR Capsules USP & Clarithromycin Tablets USP
Teva Pharmaceutical Ind. Ltd.
Jerusalem, 91010, Israel

Amoxicillin Capsules USP
Teva Canada Limited
Toronto, Canada M1B 2K9

RECALLED BY:
Teva Pharmaceuticals USA
Sellersville, PA 18960

SEE ATTACHED STOCK RESPONSE FOR LOT NUMBERS

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above mentioned product of **Lansoprazole DR Capsules USP 30mg, Amoxicillin Capsules USP 500mg, & Clarithromycin Tablets USP 500mg (Triple Therapy)** distributed under the **Teva Pharmaceuticals label.** This recall is being carried out to the **RETAIL LEVEL** due to out of specification for impurities test results obtained during stability testing for Lansoprazole. The probability of significant adverse health consequences is considered to be remote.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the specified lots of **Lansoprazole DR Capsules USP 30mg, Amoxicillin Capsules USP 500mg, & Clarithromycin Tablets USP 500mg (Triple Therapy).**
- Our records indicate we shipped this product between September 9, 2013 and February 5, 2014.
- Immediately discontinue distribution of the specific lots being recalled.
- **Please perform a SUB-RECALL to your RETAIL accounts using this Recall Notification and Stock Response Form.**
- Promptly complete the attached recall stock response and reply via fax number 817-868-5362 or mail, even if you have **no** product to return.

Completed Recall Stock Response forms can be mailed, emailed, or sent via FAX to Inmar Attn: Recall Coordinator, 4332 Empire Road Suite 200, Fort Worth, TX 76155. Inmar Email address: recallnotice@inmar.com. Inmar FAX: 817-868-5362. Inmar will send a Return Goods Authorization label and shipping label. 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 your credit.

This recall is being made with the knowledge of the Food & Drug Administration. Your cooperation and prompt response to this notice is appreciated. If you have Customer Service related questions, please contact Teva Customer Service at 800-545-8800. For medical-related questions please contact Medical Affairs at 888-838-2872, option 9. If you need a Recall Stock Response form, contact Inmar at 800-967-5952 or acquire it from clsnetlink.com.

Sincerely,

Christopher A. Murdock, PhD
Sr. Director, Regulatory Compliance
Teva Pharmaceuticals USA, Inc.

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STOCK RESPONSE FORM

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	Quantity to Return NDC 0093-8055-14 # Carton of 14 cards	Quantity to Return NDC 0093-8055-78 # Individual cards
35427772A	4/2014		
35427773A	4/2014		
35427774A	4/2014		
35427916A	4/2014		
35428048A	4/2014		
35428051A	4/2014		
35428127A	7/2014		
35428218A	7/2014		
35429573A	2/2015		
35429574A	2/2015		
35429575A	2/2015		
35429697A	3/2015		
35430184A	4/2015		

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:

Inquiries regarding this recall are to be directed to the following:

Recall Stock Response forms - If your return kit is not received between 7-10 business days contact Inmar at 800-967-5952, Option 1 then Option 3. Please **do not resubmit** response form.

Customer service related questions - contact Teva Customer Services at 800-545-8800

Medical related questions - contact Medical Affairs 888-838-2872, option 9

Please fax this form to: 817-868-5362 or E-mail at: recallnotice@inmar.com

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