

Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 6/18/13

Amoxicillin for Oral Suspension, USP 200 mg/5mL

MANUFACTURED BY:
Teva Canada Limited
Toronto, Canada M1B 2K9

RECALLED BY:
Teva Pharmaceuticals USA, Inc.
Sellersville, PA 18960

Lot #	Exp Date	Size	NDC #
35426554A	8/2014	100mL	0093-4160-73
35426555A	8/2014	100mL	0093-4160-73
35426556A	8/2014	100mL	0093-4160-73
35426557A	8/2014	75mL	0093-4160-78
35426558A	8/2014	75mL	0093-4160-78

Dear Customer:

Teva Pharmaceuticals USA, Inc. is taking the precautionary measure of voluntarily recalling the above lots of **Amoxicillin for Oral Suspension, USP 200 mg/5mL** distributed under the **Teva Pharmaceuticals** label. This recall is being carried out to the **RETAIL LEVEL** due to an orange to brown discolored Amoxicillin powder on the inner foil seal of the bottles.

Based on the previous investigation the discolored material on the inner foil seal is Amoxicillin FOS powder from the bottle. Amoxicillin FOS is a penicillin antibiotic commonly used for the treatment of infections due to susceptible strains of designated bacteria. The amount of discolored material in each bottle is very small as compared to the total amount of amoxicillin powder in each bottle. Based on the available information and for the reasons stated above, the adverse health effects are expected to be none.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the specified lots of **Amoxicillin for Oral Suspension, USP 200 mg/5mL**.
- Our records indicate we shipped this product between October 26, 2012 and May 24, 2013.
- 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 800-227-7522, 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.

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	Size	NDC #	Quantity to Return
35426554A	8/2014	100mL	0093-4160-73	
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35426558A	8/2014	75mL	0093-4160-78	

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 800-227-7522, Option 9

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

Inmar/MedTurn Use Only: _____

Scan	Labels	Store	Kit	D.B
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