

Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL - RETAIL LEVEL - INITIATED 3/28/17

PrednisoLONE Oral Solution USP, 15 mg/5 mL

RECALLED BY:

Teva Pharmaceuticals USA, Inc.
Horsham, PA 19044

Lot #	Exp. Date	Strength	Size	NDC
94358	5/2017	15 mg/5 mL	240 mL Bottle	0093-6118-87
94920A	7/2017	15 mg/5 mL	240 mL Bottle	0093-6118-87
97083A	12/2017	15 mg/5 mL	240 mL Bottle	0093-6118-87

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lots of **PrednisoLONE Oral Solution USP, 15 mg/5 mL** distributed under the **Teva Pharmaceuticals label**. This recall is being carried out to the **RETAIL LEVEL** due to out of specification alcohol content test results obtained during stability testing. The use of or exposure to the product is not expected to have adverse health consequences.


Please perform the following activities:

- Examine your inventory immediately for the specified lots of **PrednisoLONE Oral Solution USP, 15 mg/5 mL**.
- Our records indicate we shipped this product to you from July 6, 2015 to November 4, 2016.
- Immediately discontinue distribution of the specific lot numbers 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: rxrecalls@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 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 (Hours of Operation: Live calls received: Monday-Friday, 8:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week). For medical-related questions please contact Medical Information at 888-838-2872, option 3, then option 4. (Hours of Operation: Live calls received: Monday-Friday, 8:00AM-5:00 PM Eastern Time; Voicemail: 24hrs/day, 7days/week). For product quality complaint-related questions please contact Quality Assurance Services at 888-838-2872, option 3, then, option 3 (Hours of Operation: Live calls received: Monday-Friday, 9:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week). If you need a Recall Stock Response form, contact Inmar at 800-967-5952 (Hours of Operation: Monday-Friday, 8:00AM-5:00PM Eastern Time) or acquire it from clsnetlink.com.

Sincerely,



Christopher J. Unger
Regulatory Compliance
Teva Pharmaceuticals USA, Inc.

Teva Pharmaceuticals USA, Inc.

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PrednisoLONE Oral Solution USP, 15 mg/5 mL

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	Strength	Size	Quantity to Return NDC 0093-6118-87 (Count partials as 1)
94358	5/2017	15 mg/5 mL	240 mL Bottle	
94920A	7/2017	15 mg/5 mL	240 mL Bottle	
97083A	12/2017	15 mg/5 mL	240 mL Bottle	

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 (Hours of Operation: Monday-Friday, 8:00AM-5:00PM Eastern Time)

Please **do not resubmit** response form.

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

(Hours of Operation: Live calls received: Monday-Friday, 8:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week)

Medical-related questions - contact Medical Information at 888-838-2872, option 3, then option 4

(Hours of Operation: Live calls received: Monday-Friday, 8:00AM-5:00 PM Eastern Time; Voicemail: 24hrs/day, 7days/week)

Product quality complaint-related questions please contact Quality Assurance Services at 888-838-2872, option 3, then, option 3

(Hours of Operation: Live calls received: Monday-Friday, 9:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week)

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

Inmar/MedTurn Use Only:

Scan	Labels	Store	Kit	D.B
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