

Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL - RETAIL LEVEL - INITIATED 2/7/17

Buprenorphine and Naloxone Sublingual Tablets 8mg/2mg

RECALLED BY:

Teva Pharmaceuticals USA, Inc.
Horsham, PA 19044

Lot #	Exp. Date	Strength	Size	NDC
30227056A	3/2017	8mg/2mg	30 Count Bottle	0093-5721-56

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lot of **Buprenorphine and Naloxone Sublingual Tablets 8mg/2mg** distributed under the **Teva Pharmaceuticals label**. This recall is being carried out to the RETAIL LEVEL due to out of specification test results for related compounds largest unknown impurity. The probability of significant adverse health consequences is low.

Please perform the following activities:

- Examine your inventory immediately for the specified lot of **Buprenorphine and Naloxone Sublingual Tablets 8mg/2mg**
- Our records indicate we shipped this product to you from December 2, 2015 to December 21, 2015.
- Immediately discontinue distribution of the specific lot 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-7:00 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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Buprenorphine and Naloxone Sublingual Tablets 8mg/2mg

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 0093-5721-56 (Count partials as 1)
30227056A	3/2017	8mg/2mg	30 Count 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-7:00 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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