

# Teva Pharmaceuticals USA, Inc.

## URGENT DRUG RECALL – Retail LEVEL - INITIATED 9/22/16

### PARICALCITOL Capsules, 1, 2 and 4 mcg

#### RECALLED BY:

Teva Pharmaceuticals USA, Inc.  
Horsham, PA 19044

Lots #	Exp. Date	Strength	Bottle Size	NDC
13013.013A	04/2017	1 mcg	30 count	0093-7656-56
13016.011A	03/2017	2 mcg	30 count	0093-7657-56
13010.006A	09/2016	4 mcg	30 count	0093-7658-56
13010.007A	05/2017	4 mcg	30 count	0093-7658-56

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lots of **PARICALCITOL Capsules, 1, 2 and 4 mcg** distributed under the **Teva Pharmaceuticals label**. This recall is being carried out to the **Retail LEVEL** due to out of specification test results for impurities during stability testing. The use of or exposure to the product is not likely to cause adverse health consequences, but the health risk cannot be completely excluded for the target patient population.

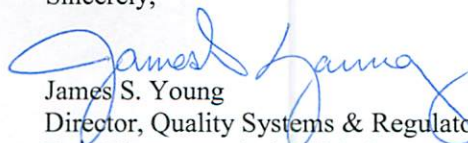
Wholesalers / Distributors / Retailers - Please perform the following activities:

- Examine your inventory immediately for the specified lots of **PARICALCITOL Capsules, 1, 2 and 4 mcg**
- Our records indicate we shipped this product between December 27, 2014 and March 7, 2016.
- 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: [rxrecalls@inmar.com](mailto: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 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 (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-4:30PM 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](http://clsnetlink.com).

Sincerely,



James S. Young  
Director, Quality Systems & Regulatory Compliance  
Teva Pharmaceuticals USA, Inc.

# Teva Pharmaceuticals USA, Inc.

## URGENT DRUG RECALL – Retail LEVEL - INITIATED 9/22/16

### PARICALCITOL Capsules, 1, 2 and 4 mcg

#### 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	Bottle Size	NDC	Quantity to Return (count partial as 1)
13013.013A	04/2017	1 mcg	30 count	0093-7656-56	
13016.011A	03/2017	2 mcg	30 count	0093-7657-56	
13010.006A	09/2016	4 mcg	30 count	0093-7658-56	
13010.007A	05/2017	4 mcg	30 count	0093-7658-56	

**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 888-838-2872, option 3, then, option 4

(Hours of Operation: Live calls received: Monday-Friday, 8:00AM-4:30PM 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](mailto:rxrecalls@inmar.com)**

Inmar/MedTurn Use Only: \_\_\_\_\_

Scan	Labels	Store	Kit	D.B
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