# Teva Pharmaceuticals USA, Inc.

## URGENT DRUG RECALL - RETAIL LEVEL - INITIATED 12/1/2016

## Risedronate Sodium Delayed-release Tablets, 35 mg

**RECALLED BY:**
**Teva Pharmaceuticals USA, Inc.**
**Horsham, PA 19044**

| Lot # | Exp. Date | Strength | Size | NDC |
|---|---|---|---|---|
| 34027040A | 10/2017 | 35 mg | Unit-Dose Carton of 4 Tablets | 0093-5509-44 |
| 34027040A | 10/2017 | 35 mg | Single Blister Pack of 1 Tablet | 0093-5509-19 |

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lot of **Risedronate Sodium Delayed-release Tablets, 35 mg** distributed under the **Teva Pharmaceuticals label.** This recall is being carried out to the RETAIL LEVEL due to an out of specification dissolution test result obtained during stability testing. The use of the product might potentially cause minor health consequences, such as temporarily reduced effectiveness, in some patients.

This product is distributed in Unit-Dose Cartons of 4 Tablets, NDC 0093-5509-44. The Carton contains 4 Single Blister Packs of 1 Tablet individually labelled NDC 0093-5509-19.

Please perform the following activities:

- Examine your inventory immediately for the specified lot of **Risedronate Sodium Delayed-release Tablets, 35 mg**
- Our records indicate we shipped this product to you from April 8, 2016 to June 27, 2016.
- Immediately discontinue distribution of the specific lot number 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.

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## Risedronate Sodium Delayed-release Tablets, 35 mg

## 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 | Quantity to Return NDC 0093-5509-44 Unit-Dose Carton of 4 Tablets | Quantity to Return NDC 0093-5509-19 Single Blister Pack of 1 Tablet |
|---|---|---|---|---|
| 34027040A | 10/2017 | 35 mg | | |

**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 |