

Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 5/29/14

Fluvastatin Capsules USP, 20 mg - 30 Count Bottle only

MANUFACTURED BY:
Teva Pharmaceutical Ind. Ltd.
Jerusalem, 91010 IL

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

| Lot # | Exp. Date | Strength | Bottle Size | NDC |
|--------|-----------|----------|-------------|--------------|
| F47008 | 7/2015 | 20 mg | 30 count | 0093-7442-56 |

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lot of **Fluvastatin Capsules USP, 20 mg** distributed under the **Teva label**. This recall is being carried out to the **RETAIL LEVEL** due a customer complaint trend regarding capsule breakage. The use of or exposure to this product may cause temporary adverse events that are medically reversible. The probability of serious adverse health consequences is remote.

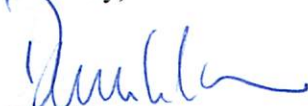
Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the specified lot of **Fluvastatin Capsules USP, 20 mg**.
- Our records indicate we shipped this product between August 20, 2013 and February 26, 2014.
- 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: 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 Information at 888-838-2872, Option 9. If you need a Recall Stock Response form, contact Inmar at 800-967-5952 or acquire it from clsnetlink.com.

Sincerely,



David L. Roberts
Director, Quality Systems
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 | Strength | Bottle Size | NDC | Quantity to Return (count partial as 1) |
|--------|-----------|----------|-------------|--------------|--|
| F47008 | 7/2015 | 20 mg | 30 count | 0093-7442-56 | |

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. Please **do not resubmit** response form.

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

Medical-related questions - contact Medical Information 888-838-2872, 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 |
|------|--------|-------|-----|-----|