

Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 3/4/14

Duloxetine DR Capsules USP, 20 mg, 30 mg & 60 mg

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

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

Strength	NDC#	Bottle Size
20 mg	0093-7542-06	60 Count
30 mg	0093-7543-56	30 Count
60 mg	0093-7544-56	30 Count

SEE ATTACHED STOCK RESPONSE FOR LOT NUMBERS

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above referenced product of **Duloxetine DR Capsules USP, 20 mg, 30 mg & 60 mg** distributed under the **Teva Pharmaceuticals** label. This recall is being carried out to the **RETAIL LEVEL** due to 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 likely remote.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for the specific lots of **Duloxetine DR Capsules USP, 20 mg, 30 mg & 60 mg** noted on the attached Stock Response Form.
- Our records indicate we shipped this product between December 11, 2013 and February 22, 2014.
- Immediately discontinue distribution of all recalled lots.
- **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 Affairs 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,



Christopher A. Murdock, PhD
Sr. Director, Regulatory Compliance
Teva Pharmaceuticals USA, Inc.

Teva Pharmaceuticals USA, Inc.

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STOCK RESPONSE FORM – Page 1 of 2

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	NDC#	Quantity to Return (count partials as 1)
48D001	5/2015	20mg	0093-7542-06	
48D002	9/2015	20mg	0093-7542-06	
49D001	4/2015	30mg	0093-7543-56	
49D002	6/2015	30mg	0093-7543-56	
49D003	7/2015	30mg	0093-7543-56	
49D004	9/2015	30mg	0093-7543-56	
49D005	9/2015	30mg	0093-7543-56	
49D006	9/2015	30mg	0093-7543-56	
49D007	10/2015	30mg	0093-7543-56	
50D003	2/2015	60mg	0093-7544-56	
50D004	3/2015	60mg	0093-7544-56	
50D005	3/2015	60mg	0093-7544-56	
50D006	5/2015	60mg	0093-7544-56	
50D010	6/2015	60mg	0093-7544-56	
50D028	9/2015	60mg	0093-7544-56	
50D029	10/2015	60mg	0093-7544-56	
50D031	10/2015	60mg	0093-7544-56	
50D032	11/2015	60mg	0093-7544-56	
50D033	11/2015	60mg	0093-7544-56	

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STOCK RESPONSE FORM – Page 2 of 2

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 Services at 800-545-8800

Medical related questions - contact Medical Affairs 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
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