

**Teva Pharmaceuticals USA Inc.**  
**URGENT DRUG RECALL – RETAIL LEVEL – INITIATED 01/25/2011**  
**Lisinopril Tablets USP, 10mg, 20mg and 40mg**

**MANUFACTURED BY:**  
**Emcure Pharmaceuticals Ltd.**  
**Hinjwadi Pune, India**

**RECALLED BY:**  
**Teva Pharmaceuticals USA**  
**Sellersville, PA 18960**

**Lisinopril Tablets USP, 10mg**  
**NDC# 0172-3759-80, 1000 count bottles**

**Lisinopril Tablets USP, 20mg**  
**NDC# 0172-3760-60, 100 count bottles**  
**NDC# 0172-3760-70, 500 count bottles**  
**NDC# 0172-3760-80, 1000 count bottles**

**Lisinopril Tablets USP, 40mg**  
**NDC# 0172-3761-60, 100 count bottles**  
**NDC# 0172-3761-70, 500 count bottles**

***SEE ATTACHED STOCK RESPONSE FOR LOT NUMBERS***

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above mentioned lots of **Lisinopril Tablets USP, 10mg, 20mg and 40mg** distributed under the **Teva Pharmaceuticals label**. This recall is being carried out to the RETAIL LEVEL due to the potential that some tablets may exhibit areas of discoloration.


Wholesalers / Distributors - Please perform the following activities:

- Please examine your inventory immediately for the specified lots of **Lisinopril Tablets USP, 10mg, 20mg and 40mg**.
- Our records indicate we shipped this product between July 14, 2010 and November 22, 2010.
- Immediately discontinue distribution of the product 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 817-868-5343 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: [rarequest@inmar.com](mailto:rarequest@inmar.com). Inmar FAX: 817-868-5343. 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 Services at 800-545-8800. Medical related questions, please contact Teva Medical Affairs at 215-641-6974. If you need a Recall Stock Response form, contact Inmar at 800-967-5952.

Sincerely,

 **Sean M. Israel**

Director, Regulatory Compliance  
Teva Pharmaceuticals USA, Inc.

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## **RECALL RESPONSE FORM** (Page 1 of 3)

### **Lisinopril Tablets USP, 10mg, 20mg and 40mg**

**Please fill out completely and submit all 3 pages**

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 #: \_\_\_\_\_

#### **Lisinopril Tablets USP, 10mg**

<b>Lot #</b>	<b>Exp. Date</b>	<b>Size</b>	<b>NDC #</b>	<b>Qty. to Return (Bottles)</b>
TE05051	5/2012	1000 count	0172-3759-80	
TE05061	5/2012	1000 count	0172-3759-80	
TE05094	5/2012	1000 count	0172-3759-80	
TE05098	5/2012	1000 count	0172-3759-80	
TE05108	5/2012	1000 count	0172-3759-80	
TE06021	6/2012	1000 count	0172-3759-80	
TE06022	6/2012	1000 count	0172-3759-80	
TE06209	7/2012	1000 count	0172-3759-80	

#### **Lisinopril Tablets USP, 20mg**

<b>Lot #</b>	<b>Exp. Date</b>	<b>Size</b>	<b>NDC #</b>	<b>Qty. to Return (Bottles)</b>
TE07109	7/2012	100 count	0172-3760-60	
TE08053	8/2012	100 count	0172-3760-60	
TE07110	7/2012	500 count	0172-3760-70	
TE07118	7/2012	500 count	0172-3760-70	
TE07127	7/2012	500 count	0172-3760-70	
TE07237	7/2012	1000 count	0172-3760-80	
TE07238	7/2012	1000 count	0172-3760-80	
TE07263	7/2012	1000 count	0172-3760-80	
TE07271	7/2012	1000 count	0172-3760-80	
TE07272	7/2012	1000 count	0172-3760-80	
TE07309	8/2012	1000 count	0172-3760-80	
TE07310	8/2012	1000 count	0172-3760-80	
TE07311	8/2012	1000 count	0172-3760-80	
TE08052	8/2012	1000 count	0172-3760-80	
TE08108	8/2012	1000 count	0172-3760-80	
TE08120	8/2012	1000 count	0172-3760-80	
TE08129	8/2012	1000 count	0172-3760-80	
TE08139	8/2012	1000 count	0172-3760-80	
TE08204	9/2012	1000 count	0172-3760-80	
TE08205	9/2012	1000 count	0172-3760-80	
TE09080	9/2012	1000 count	0172-3760-80	

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## **RECALL RESPONSE FORM (Page 2 of 3)**

### **Lisinopril Tablets USP, 10mg, 20mg and 40mg**

#### **Lisinopril Tablets USP, 40mg**

<b>Lot #</b>	<b>Exp. Date</b>	<b>Size</b>	<b>NDC #</b>	<b>Qty. to Return (Bottles)</b>
TE04168A	4/2012	100 count	0172-3761-60	
TE04203A	4/2012	100 count	0172-3761-60	
TE04221A	4/2012	100 count	0172-3761-60	
TE06208	7/2012	100 count	0172-3761-60	
TE06225	7/2012	100 count	0172-3761-60	
TE07218	7/2012	100 count	0172-3761-60	
TE07219	8/2012	100 count	0172-3761-60	
TE04168B	4/2012	500 count	0172-3761-70	
TE04203B	4/2012	500 count	0172-3761-70	
TE04221B	4/2012	500 count	0172-3761-70	
TE06065	6/2012	500 count	0172-3761-70	
TE06066	6/2012	500 count	0172-3761-70	
TE06072	6/2012	500 count	0172-3761-70	
TE06083	6/2012	500 count	0172-3761-70	
TE06084	6/2012	500 count	0172-3761-70	
TE06119	6/2012	500 count	0172-3761-70	
TE06132	6/2012	500 count	0172-3761-70	
TE06176	6/2012	500 count	0172-3761-70	
TE06177	6/2012	500 count	0172-3761-70	
TE06178	6/2012	500 count	0172-3761-70	
TE06207	7/2012	500 count	0172-3761-70	
TE07019	7/2012	500 count	0172-3761-70	
TE07052	7/2012	500 count	0172-3761-70	
TE07092	7/2012	500 count	0172-3761-70	
TE07093	7/2012	500 count	0172-3761-70	
TE07095	7/2012	500 count	0172-3761-70	
TE07136	7/2012	500 count	0172-3761-70	
TE07148	7/2012	500 count	0172-3761-70	
TE07161	7/2012	500 count	0172-3761-70	

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## **RECALL RESPONSE FORM (Page 3 of 3)**

### **Lisinopril Tablets USP, 10mg, 20mg and 40mg**

**Customers who did not purchase the product directly from the manufacturer must complete the following:**

Purchased From: Name \_\_\_\_\_ DEA #: \_\_\_\_\_  
Address: \_\_\_\_\_  
City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

**I have checked my stock and:**

\_\_\_\_\_ I do not have any stock of the recalled items.

**OR**

I have quarantined and listed in the Stock Response Forms provided the quantity of units of **Lisinopril Tablets USP, 10mg, 20mg and 40mg** and will be returning to Inmar. Upon receipt of this Stock Response Form, Inmar, will issue a recall return authorization and shipping label(s) \_\_\_\_\_ (please indicate the # of box labels needed)

**Inquiries regarding this recall are to be directed to the following:**

Recall Stock Response forms **OR** product return information only - contact Inmar at 1-800-967-5952

Customer service related questions - contact Teva Customer Services at 1-800-545-8800

Medical related questions - contact Teva Medical Affairs 215-641-6974

**Please fax this form to: 1-817-868-5343 or E-mail at: rarequest@inmar.com**

Inmar/MedTurn Use Only:

Scan	Labels	Store	Kit	D.B
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