

Teva Pharmaceuticals USA, Inc.

Amended – Corrected Expiry Date on Stock Response Form

URGENT DRUG RECALL – RETAIL LEVEL - AMENDED 11/15/13

Fluconazole for Oral Suspension, 10 mg/mL

MANUFACTURED BY:

Cipla Ltd.
Goa, India

RECALLED BY:

Teva Pharmaceuticals USA, Inc.
Sellersville, PA 18960

ALL LOTS WITH EXPIRY DATE THROUGH 05/2015

Fluconazole for Oral Suspension, 10 mg/mL
NDC# 0093-5414-95, 35 mL Bottles

SEE ATTACHED STOCK RESPONSE FOR LOT NUMBERS

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above referenced product of Fluconazole for Oral Suspension, 10 mg/mL distributed under the Teva Pharmaceuticals label. This recall is being carried out to the **RETAIL LEVEL** due to the potential for some lots to be below specification for preservative content throughout shelf life. The probability to experience adverse health effects is estimated as low. This recall was initiated 11/14/2013 and is amended to correct an expiry date list on the stock response form below.

Wholesalers / Distributors - Please perform the following activities:

- Examine your inventory immediately for lots of **Fluconazole for Oral Suspension, 10 mg/mL**.
- Our records indicate we shipped this product between February 22, 2012 and October 31, 2013.
- Immediately discontinue distribution of all 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: 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.
***Amended – Corrected Expiry Date on Stock Response Form**
URGENT DRUG RECALL – RETAIL LEVEL - AMENDED 11/15/13
Fluconazole for Oral Suspension, 10 mg/mL

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 #: _____

NDC# 0093-5414-95, 35 mL Bottles

Lot No.	Expiry	Amt. Returned (Partials Count as 1)	Lot No.	Expiry	Amt. Returned (Partials Count as 1)	Lot No.	Expiry	Amt. Returned (Partials Count as 1)
V10316	11/13		V20182	4/14		V20370	10/14	
V10317	11/13		V20203	5/14		V20410	11/14	
V10320	11/13		V20204	5/14		V20411	11/14	
V10321	11/13		V20233	5/14		V20412	11/14	
V20087	2/14		V20234	5/14		V30009	12/14	
V20089	2/14		V20273	6/14		V30010	12/14	
V20093	2/14		V20274	6/14		V30011	12/14	
V20094	2/14		V20275	6/14		V30056	1/15	
V20086	2/14		V20293	8/14		V30120	2/15	
V20118	3/14		V20294	8/14		V30122	2/15	
V20119	3/14		V20321	9/14		V30123	2/15	
V20147	3/14		V20322	9/14		V30163	3/15	
V20148	3/14		V20323	9/14		V30164	3/15	
V20152	4/14		V20324	9/14		V30165	3/15	
V20154	4/14		V20325	9/14		V30190	3/15	
V20155	4/14		V20326	9/14		V30249	5/15	
V20180	4/14		V20327	9/14 *		V30250	5/15	
V20181	4/14		V20369	10/14				

* Corrected Expiry

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
------	--------	-------	-----	-----