

# Teva Pharmaceuticals USA, Inc.

## URGENT DRUG RECALL - RETAIL LEVEL - INITIATED 4/24/17

### Clozapine Tablets USP, 25 mg

**RECALLED BY:**

Teva Pharmaceuticals USA, Inc.  
Horsham, PA 19044

Lot #	Exp. Date	Strength	Pack Size	NDC
07C160	3/2018	25 mg	100 Count Bottle	0093-4359-01
07C160	3/2018	25 mg	500 Count Bottle	0093-4359-05
07C160A	3/2018	25 mg	100 Unit Dose Blisters/Carton	0093-4359-93
07C160A	3/2018	25 mg	Individual Blister Pack	0093-4359-19

Dear Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lots of **Clozapine Tablets USP, 25 mg** distributed under the **Teva Pharmaceuticals label**. This recall is being carried out to the RETAIL LEVEL due to the presence of mold that was identified in a customer complaint sample of one distributed 500-count bottle. As a precautionary measure this recall includes all packaging configurations. The use of or exposure to the product might have adverse health consequences but the probability appears low.

This product is distributed as Unit-Dose Cartons of 100 Tablets, NDC 0093-4359-93. Each tablet in the carton is packaged in a single blister pack and individually labelled with NDC 0093-4359-19.

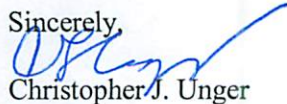
Please perform the following activities:

- Examine your inventory immediately for the specified lots of **Clozapine Tablets USP, 25 mg**
- Our records indicate we shipped this product to you from August 1, 2016 to March 28, 2017.
- Immediately discontinue distribution of the specific lot numbers 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](mailto: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 888-483-8279, option 2 (Hours of Operation: Live calls received: Monday-Friday, 8:00AM-5:00 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](http://clsnetlink.com).

Sincerely,



Christopher J. Unger  
Regulatory Compliance  
Teva Pharmaceuticals USA, Inc.

# Teva Pharmaceuticals USA, Inc.

## URGENT DRUG RECALL - RETAIL LEVEL - INITIATED 4/24/17

### Clozapine Tablets USP, 25 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	Pack Size	NDC	Quantity to Return (count partial as 1)
07C160	3/2018	25 mg	100 Count Bottle	0093-4359-01	
07C160	3/2018	25 mg	500 Count Bottle	0093-4359-05	
07C160A	3/2018	25 mg	100 Unit Dose Blisters/Carton	0093-4359-93	
					Quantity to Return
07C160A	3/2018	25 mg	Individual Blister Pack	0093-4359-19	

**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 888-483-8279, option 2  
(Hours of Operation: Live calls received: Monday-Friday, 8:00AM-5:00 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](mailto:rxrecalls@inmar.com)**

Inmar/MedTurn Use Only:

Scan	Labels	Store	Kit	D.B
------	--------	-------	-----	-----