

Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 11/9/17

Clozapine Tablets USP, 100 mg

RECALLED BY:

Teva Pharmaceuticals USA, Inc.
Horsham, PA 19044

Lot #	Exp. Date	Strength	Bottle Size	NDC
39C192	06/2019	100 mg	500 count	0093-7772-05

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lot of **Clozapine Tablets USP, 100 mg** distributed under the **Teva Pharmaceuticals label**. This recall is being carried out to the RETAIL LEVEL due to the potential presence of broken tablets. The use of or exposure to the product might have adverse health consequences if a patient ingests a large number of broken tablets consecutively. The probability of actually taking broken tablets by patients appears to be very low.

Wholesalers / Distributors / Retailers - Please perform the following activities:

- Examine your inventory immediately for the specified lot of **Clozapine Tablets USP, 100 mg**
- Our records indicate we shipped this product between August 8, 2017 and September 19, 2017.
- Immediately discontinue distribution of the specific lot being recalled.
- **Wholesalers/Distributors/Retailers, if you have further distributed the specific lot, please perform a SUB-RECALL to your RETAIL accounts using this Recall Notification and Stock Response Form.**
- Even if you have no product to return, promptly complete the attached recall stock response form (SRF) and return by mail, email, or FAX to Inmar, Attn: Recall Coordinator,
Inmar, 635 Vine Street, Winston Salem, NC 27101.
Email address: rxrecalls@inmar.com.
FAX: 817-868-5362.

Inmar will send a Return Goods Authorization label and shipping label if requested on your SRF. 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. Products returned that are not the subject of the recall will not be credited and will be destroyed.

CONTACT INFORMATION AND CREDIT
<u>Product Returns:</u> Contact Inmar at: 800-967-5952. (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response forms Contact Inmar at: 800-967-5952 or acquire it from clsnetlink.com .
<u>Customer Service-related Questions:</u> Contact Teva Customer Service: 800-545-8800 (Hours of Operation: Live calls received: Monday-Friday, 8:30AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week).
<u>Medical-related Questions or to report an Adverse Event:</u> Contact Medical Information at: 888-483-8279 Live calls received: Monday-Friday, 9:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week
<u>Product Quality Complaint-related Questions:</u> Contact Quality Assurance Services: 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).
FDA contact information for reporting adverse events/quality complaints: Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088

Sincerely,

Regulatory Compliance
Teva Pharmaceuticals USA, Inc.

Teva Pharmaceuticals USA, Inc.

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Clozapine Tablets USP, 100 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	Bottle Size	NDC	Quantity to Return (count partial as 1)
39C192	06/2019	100 mg	500 count	0093-7772-05	

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: _____

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Customer Service-related Questions:

Contact Teva Customer Service: 800-545-8800

(Hours of Operation: Live calls received: Monday-Friday, 8:30AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week).

Medical-related Questions or to report an Adverse Event:

Contact Medical Information at: 888-483-8279

Live calls received: Monday-Friday, 9:00AM-5:00PM Eastern Time; Voicemail: 24hrs/day, 7days/week

Product Quality Complaint-related Questions:

Contact Quality Assurance Services: 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).

FDA contact information for reporting adverse events/quality complaints:

Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088

Please FAX this form to: 817-868-5362 or E-mail at: rxrecalls@inmar.com or mail to:

Inmar, Attn: Recall Coordinator, Inmar, 635 Vine Street, Winston Salem, NC 27101.

Inmar/MedTurn Use Only:

Scan	Labels	Store	Kit	D.B
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