

# Teva Pharmaceuticals USA, Inc.

## URGENT DRUG RECALL – Extension to RETAIL LEVEL – 10/18/2018

### Clonazepam Orally Disintegrating Tablets USP, 2 mg

**RECALLED BY:**

**Teva Pharmaceuticals USA, Inc.  
North Wales, PA 19454**

Lot #	Exp. Date	Strength	Bottle Size	NDC
34033752A	1/2020	2 mg	60 Count Carton	0555-0098-96

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is extending its voluntary recall of the above lot of **Clonazepam Orally Disintegrating Tablets USP, 2 mg** to the **RETAIL LEVEL** that was originally initiated on 9/21/2018. The specified product was distributed under the **Teva Pharmaceuticals USA, Inc. label**. The reason for the recall is due to an out of specification test result for water content obtained during routine stability testing activities. The use of or exposure to the product is not expected to have adverse health consequences.

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

- Immediately examine your inventory for the specified lot of **Clonazepam Orally Disintegrating Tablets USP, 2 mg**
- Our records indicate we shipped this product between June 4, 2018 and July 31, 2018.
- 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](mailto: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 a credit. Products returned that are not the subject of the recall will not be credited and will be destroyed.

#### CONTACT INFORMATION AND CREDIT

Product Returns: 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](http://clsnetlink.com).

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: 24 hrs./day, 7 days/week).

Medical-related Questions or to report an Adverse Event:

Contact Medical Information at: 888-838-2872, option 3, then, option 4  
Live calls received: Monday-Friday, 9:00 AM-5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/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: 24 hrs./day, 7 days/week).

FDA contact information for reporting adverse events/quality complaints:

Online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm) or call FDA at 1-800-FDA-1088

Sincerely,

Regulatory Compliance  
Teva Pharmaceuticals USA, Inc.

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#### 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)
34033752A	1/2020	2 mg	60 Count Carton	0555-0098-96	

**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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**Please FAX this form to: 817-868-5362 or E-mail at: [rxrecalls@inmar.com](mailto: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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