URGENT DRUG RECALL

Cyclobenzaprine Hydrochloride Tablets, USP 7.5 mg

INITIATED 07/29/2021

Teva Pharmaceuticals USA, Inc.

NDC	Product Description	Lot#	Exp. Date
0591-3330-01	Cyclobenzaprine Hydrochloride Tablets, USP 7.5 mg 100 Count	1408821A	08/2023

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling above reference lot of **Cyclobenzaprine Hydrochloride Tablets, USP 7.5 mg** to the RETAIL LEVEL that was distributed under the Actavis Pharma Inc., label.

This recall is being initiated because an out of specification (OOS) test result for Total Aerobic Microbial Count (TAMC) and Total Yeast and Mold Count (TYMC) was obtained during annual retesting for an excipient batch of Dibasic Calcium Phosphate. This excipient batch was used in the manufacturing of the above referenced finished product lot. It is important to note that the excipient batch met all test specifications including TAMC and TYMC prior to release for manufacturing of finished product. Based on the health hazard assessment, the likelihood of occurrence is remote. However, exposure to the product of concern could lead to mild adverse events.

This recall is being made with the knowledge of the Food and Drug Administration.

Please perform the following activities that are necessary for this recall:

- Immediately examine your inventory for the specified lot of Cyclobenzaprine Hydrochloride Tablets, USP 7.5 mg.
- Immediately discontinue distribution of the product lot affected by this recall.
- Our records indicate Teva USA shipped the lot to its customers from January 19, 2021 through June 01, 2021.
- **If you have further distributed the lot, please perform a SUB-RECALL to your 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 labels for Return Goods Authorization (RGA) and shipping after receipt of your SRF. Appropriate credit for product returns, plus handling and shipping expenses, will be issued after receipt of said product with your RGA. All recalled product returned without a RGA 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: 855-755-8132 (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response Forms - Contact Inmar at: 855-755-8132 or acquire forms from clsnetlink.com.
Medical-related Questions or to report an Adverse Event: Contact Medical Information at: 888-838-2872, option 3, then, option 4 Live calls received: M - F, 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 4 Live calls received: M - F, 9:00 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week
Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 3 then, option 2 Live calls received: M - F, 8:30 AM - 5:00 PM 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 or call FDA at 1-800-FDA-1088

Sincerely,

Regulatory Compliance
Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL

Cyclobenzaprine Hydrochloride Tablets, USP 7.5 mg

INITIATED 07/29/2021

Teva Pharmaceuticals USA, Inc.

STOCK RESPONSE FORM

Enter the information of the recalled product to be returned in the table below. If additional space is needed, please make copies of this 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; in order to process your form.*

Address: _____

City: _____ State: _____ Zip: _____

Contact Name (please print): _____ Telephone #: _____

NDC	Lot #	Exp. Date	Quantity to Return (Count Partial Bottles as 1)
0591-3330-01	1408821A	08/2023	

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: _____

Please return this form by FAX to: 817-868-5362 or by 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