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URGENT: DRUG RECALL

THEOPHYLLINE EXTENDED-RELEASE TABLETS 600mg
100s Container pack (Tablets)
(NDC 68462-356-01)

May 9, 2025

Dear Pharmacy, Wholesale and Retail Customer:

This is to inform you that Glenmark is initiating a voluntary recall at the Retail level involving the following prescription product:

Theophylline Extended-Release Tablets 600 mg (100's Tablets)

Sr. No.	NDC Code	Batch Number	Pack Size	Expiry Date
1	68462-356-01	19234121	100's Tablets in Container	September 2025
2	68462-356-01	19234148	100's Tablets in Container	September 2025
3	68462-356-01	19242881	100's Tablets in Container	June 2026
4	68462-356-01	19242899	100's Tablets in Container	June 2026

The recall to the retail level of the above-identified Theophylline Extended-Release Tablets 600 mg batches have been initiated out of an abundance of caution due to out-of-specification results reported for the Dissolution (By UV) test for batch # 19242899 at 6 Months long-term (25°C/60% RH), batch # 19231955 at 18 months long-term (25°C/60% RH), and batch # 19234148 (Expiry: 04/2025), and 19242881 (Expiry: 04/2025) for reserve samples during impact evaluation testing. To date, Glenmark has not received any reports of adverse events related to this recall.

The Health hazard assessment concluded that the observed OOS result at the 6-month dissolution test for the product Theophylline Extended Release Tablets 600 mg is unlikely to have a significant impact on patient health and safety.

Glenmark Pharmaceuticals Inc. USA 750 Corporate Drive, Mahwah, NJ 07430
T: 1 201 684 8000 F: 1 201 831 0080 www.glenmarkpharma.com/usa

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Please see the details of product batches listed in the above table and refer to the enclosed product labels for ease in identifying the product.

Please examine your inventory and if you have any inventory available for the batches specified in the above table, you should quarantine such product immediately and not dispense any further product from these lots. Glenmark Pharmaceuticals Inc., USA initiated shipment of this product on 12/30/2023

In addition, if you are a wholesaler/ distributor, who has further distributed this product, please identify those retail customers and notify them at once of this Product recall. Your notification to your retail customers may be enhanced by including a copy of this recall notification letter. Again, this recall should be carried out to the retail level only. Because this is not a consumer level recall, notice to the consumer level is not required.

Glenmark is requesting the batches specified in the above table to be returned to Inmar Rx Solutions (address below) using the Postage Paid Product Return label that was provided in your Recall Return Packet.

Inmar Rx Solutions
3845 Grand Lakes Way
Grand Prairie, TX 75050

Please complete and return the enclosed response form preferably within 72 hours of receipt of this notification. Please either fax your response to 817-868-5362 or email to Rxrecalls@Inmar.com.

If you have any questions regarding your recall return please contact Inmar at **877-722-4316**

Inmar office hours are Monday through Friday, from 9 am to 5 pm EST.

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

Glenmark Pharmaceuticals Inc. USA 750 Corporate Drive, Mahwah, NJ 07430
T: 1 201 684 8000 F: 1 201 831 0080 www.glenmarkpharma.com/usa

Thank you for your cooperation,

Sincerely,

GLENMARK PHARMACEUTICALS INC., USA

thomas.callaghan@glenmarkpharma.com

Digitally signed by thomas.callaghan@glenmarkpharma.com
Date: 2025.05.09 12:05:54 -04'00'

Thomas Callaghan

Executive Director - Regulatory Affairs, North America

US Agent for Glenmark Pharmaceuticals Limited

Enclosure(s):

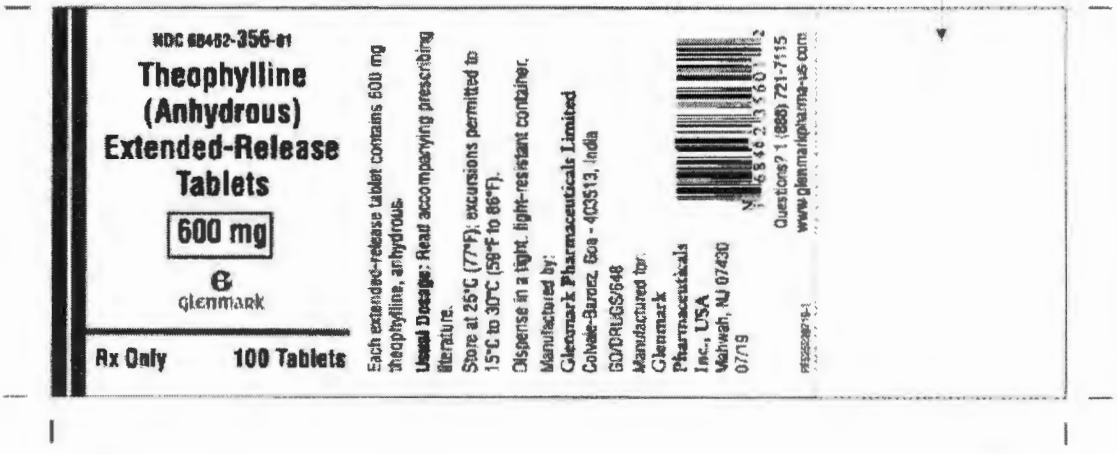
Product Labels

Recall Return Response Form

Product labels:

Theophylline Extended-Release Tablets 600 mg (100's Tablets)

JAR SIZE : 150 CC
SAME SIZE ARTWORK
LABEL SIZE : 130 mm x 50 mm



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Glenmark Pharmaceuticals Inc.
RECALL RETURN RESPONSE FORM
THEOPHYLLINE EXTENDED-RELEASE TABLETS 600mg
100s Container pack (Tablets)
(NDC 68462-356-01)
Retail Level
5/9/2025

Please fill out this form completely. By doing so, this will acknowledge that you have read and understood the recall instructions and have taken the appropriate action.

Customer Name:	DEA#:	
DEA # is required, if it is not provided, the processing of your form will be delayed.		
Address:		
City:	State:	Zip:
Contact Name (Please Print):		
Telephone#:	Email:	
Contact Signature:	Date:	
DEBIT MEMO# (If unsure, leave blank):		

Wholesaler Information if not directly purchased from Glenmark Pharmaceuticals Inc.:

Wholesaler Name:	DEA#:	
City:	State:	Zip:

I have checked my stock and communicated to my customers at the appropriate level:

□ I confirm that all locations that received the impacted products have been notified to the Retail level _____(Initial and date)

□ I do not have any stock of the recalled items. **OR**

□ I have quarantined and listed in the box below the quantity of recalled units and I will be returning to Inmar, as soon as possible. Upon receipt of this Response Form, Inmar, will issue return authorization label(s) Please indicate the # of needed box labels_____

Theophylline Extended-Release Tablets 600mg (100's Tablets)

Sr. No.	Product Name	NDC Code	Batch Number	Pack Size	Expiry Date	Total Full/ Sealed and Partial/ Open Bottle Count
1	Theophylline Extended-Release Tablets 600mg	68462-356-01	19234121	100's Tablets in Container	September 2025	
2	Theophylline Extended-Release Tablets 600mg	68462-356-01	19234148	100's Tablets in Container	September 2025	
3	Theophylline Extended-Release Tablets 600mg	68462-356-01	19242881	100's Tablets in Container	June 2026	
4	Theophylline Extended-Release Tablets 600mg	68462-356-01	19242899	100's Tablets in Container	June 2026	

If you have any questions regarding this form or product return please contact Inmar at **877-722-4316** Office hours 9am to 5pm EST Mon thru Fri.

Please fax this form to: 1-817-868-5362 or E-mail rxrecalls@inmar.com

Recall Event ID N131301/RCL096-25

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