

Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 09/05/2017

Acarbose Tablets 25 mg, 100 count bottles

RECALLED BY:

Teva Pharmaceuticals USA, Inc.
Horsham, PA 19044

Lot #	Exp. Date on label	Strength	Bottle Size	NDC
1082710A	July 2018	25 mg	100	16252-523-01

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling to the **RETAIL LEVEL** lot number 1082710A of Acarbose Tablets 25mg which was distributed under the **Actavis Pharma Inc. label**. The reason for the recall is due to an incorrect expiration date of July 2018 printed on the product labeling. The correct expiration date is July 2017. No other lots of the Acarbose 25mg are affected by this recall. The use of affected product is not expected to cause adverse health consequences.

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

- Examine your inventory immediately for **Lot Number 1082710A of Acarbose Tablets 25mg, NDC 16252-523-01**.
- Our records indicate we shipped the recalled product lot between February 15, 2016 – July, 17 2017.
- Immediately discontinue distribution of **this lot 1082710A of Acarbose Tablets 25mg, NDC 16252-523-01** being recalled.
- **Wholesalers/Distributors/Retailers, if you have further distributed the recalled lot, please perform a SUB-RECALL to the RETAIL level *only* 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

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.

Customer Service-related Questions:

Contact Teva Customer Service: 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 or to report an Adverse Event:

Contact Medical Information at: 888-838-2872, option 3, then, option 4

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

Sincerely,

Regulatory Compliance
Teva Pharmaceuticals USA, Inc.

Teva Pharmaceuticals USA, Inc.

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Acarbose Tablets 25 mg, 100 count bottles

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 (on Label)	Strength	Bottle Size	NDC	Quantity to Return (Count partials as 1)
1082710A	July 2018	25 mg	100 count	16252-523-01	

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

Inmar/MedTurn Use Only:

Scan	Labels	Store	Kit	D.B
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