URGENT DRUG RECALL
Brinzolamide Ophthalmic Suspension, USP 1%
Initiated 12/08/2021

Teva Pharmaceuticals USA, Inc.

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (Teva USA) is voluntarily recalling sixteen (16) Lots of **Brinzolamide Ophthalmic Suspension, USP 1%** to the Retail Level. Refer to Attachment I of this notification for the list of Lots being recalled. Please take the following actions given below. The affected product lots were distributed under the label of Teva Pharmaceuticals USA, Inc.

This recall has been initiated because of a dispenser (dropper) nozzle defect. Specifically, the notch in the cap that fits into the nozzle of the dropper could break off and block the dropper tip possibly resulting in the product not dispensing. The main consequence of the product not being dispensed could be missed dose(s) and treatment delay. The approved product's indications are for the treatment of elevated intraocular pressure in patients with ocular hypertension or open angle glaucoma. Delaying treatment may lead to worsening of the condition resulting in adverse events such as visual impairment or in advance cases, blindness. The patients that are at highest risk are those with advanced stage glaucoma.

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

ACTIONS: Please *promptly* perform the following actions that are necessary for this recall:

- Examine your inventory for the specified recalled product lots.
- Quarantine and cease distribution of the product lots affected by this recall.
- Teva USA distribution records indicate that NDC 00591-2127-79 was shipped from 03/08/2021 through 09/30/2021 and NDC 0591-2127-12 was shipped from 03/08/2021 through 09/27/2021.
- Even if you have **no** product to return, it is necessary that you 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.
- **If you have further distributed product lots affected by this recall please perform a SUB-RECALL to your accounts using this Recall Notification and Stock Response Form as a basis of your recall notification.**

After receipt of your completed SRF, Inmar will send labels for Return Goods Authorization (RGA) and for return shipping of the recalled merchandise. Appropriate credit for your product returns, plus handling and shipping expenses, will be issued after receipt of said product and 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: 855-863-0535 (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response Forms - Contact Inmar at 855-863-0535 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.

/enclosures: (1) Stock Response Form; (2) Attachment I – List of Recall Lots

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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** your DC locations? ☐ YES ☐ NO

Customer/Store Name:	
*DEA #:	*Debit Memo #

DEA # is required; in order to process your form.

Address: _____

City: _____ State: _____ Zip: _____

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

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.

Brinzolamide Ophthalmic Suspension, USP 1%		
NDC	**Lot**	**Quantity to Return**

Please send me _____ shipping box labels

NON DIRECT CUSTOMERS ONLY: Please complete the following:

Purchased From (Wholesaler name): _____ DEA #: _____

DEA # is required; in order to process your form.

City: _____ State: _____

Please promptly 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

Teva Pharmaceuticals USA, Inc.

Attachment I – List of Recalled Lots

Brinzolamide Ophthalmic Suspension, USP 1%			
NDC	**Lot**	**Exp. Date**	**Size**
00591-2127-79	BCB11AC2	12/2022	10 mL
00591-2127-79	BCB12AC2	12/2022	10 mL
00591-2127-79	BCB1LB2	11/2022	10 mL
00591-2127-79	BCB3AC2	12/2022	10 mL
00591-2127-79	BCB4AC2	12/2022	10 mL
00591-2127-79	BCB5AC2	12/2022	10 mL
00591-2127-79	BCB2LB2	11/2022	10 mL
00591-2127-79	BCB7LB2	11/2022	10 mL
00591-2127-79	BCB6AC2	12/2022	10 mL
00591-2127-79	BCB10AC2	12/2022	10 mL
00591-2127-12	BCB1AC2	12/2022	15 mL
00591-2127-12	BCB1DC2	03/2023	15 mL
00591-2127-12	BCB2AC2	12/2022	15 mL
00591-2127-12	BCB4LB2	11/2022	15 mL
00591-2127-12	BCB5LB2	11/2022	15 mL
00591-2127-12	BCB2DC2	03/2023	15 mL