DRUG RECALL

Lidocaine 2.5% and Prilocaine 2.5% Cream, USP

INITIATED 04/15/2022

Teva Pharmaceuticals USA, Inc.

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling specific lots of **Lidocaine 2.5% and Prilocaine 2.5% Cream, USP** to the RETAIL LEVEL. Detailed information on the lots in this recall is given in the table below.

Tube/Carton NDC	Lot #	Exp. Date	Package Description
0591-2070-30	16255	11/2022	30 gram/tube
0591-2070-30	16256	02/2024	30 gram/tube
0591-2070-30	16257	12/2022	30 gram/tube
0591-2070-30	16258	12/2022	30 gram/tube
0591-2070-30	16291	01/2024	30 gram/tube
0591-2070-30	16412	02/2024	30 gram/tube
0591-2070-30	16469	02/2024	30 gram/tube
0591-2070-30	16505	03/2024	30 gram/tube
0591-2070-30	16506	03/2024	30 gram/tube
0591-2070-30	16627	04/2024	30 gram/tube
0591-2070-30	16786	04/2024	30 gram/tube
0591-2070-30	16787	04/2024	30 gram/tube
0591-2070-30	16820	04/2024	30 gram/tube
0591-2070-72	16291	01/2024	5 gram/tube
0591-2070-72	16469	02/2024	5 gram/tube

Lidocaine 2.5% and Prilocaine 2.5% Cream, USP was distributed under the label for Actavis Pharma, Inc. NDC# 0591-2070-30 was distributed from 04 JAN 2021 through 24 NOV 2021 and NDC# 0591-2070-72 was distributed from 10 FEB 2021 through 22 DEC 2021.

This recall is being initiated because stability testing to support these products on the market has been terminated due to the closure of Teva's third party manufacturer of this product. 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 recalled product lots included in the above table and discontinue distribution.
- **If you have further distributed these lots, please perform a SUB-RECALL to your accounts. Use this Recall Notification and Stock Response Form (SRF) as a basis for your SUB-RECALL letter.**
- Even if you have **no** product to return, promptly complete the attached Recall 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** or 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 and Stock Response Forms: Contact Inmar at: 888-383-0428 (dedicated phone line). Hours of Operation: M – F, 9.00 AM to 5.00 PM Eastern Time Withdrawal Stock Response Forms - Contact Inmar at 888-383-0428 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 24 hrs. /day, 7 days/week or by email at druginfo@tevapharm.com
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.

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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** 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 #: _____

Enter NDC	Enter Lot #	Quantity to Return (tubes)

Additional Stock Response Forms included: Yes ☐ No ☐

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 #: _____

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

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