Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL – 07/14/2020

Lidocaine Patch 5%

RECALLED BY:
Teva Pharmaceuticals USA, Inc., Parsippany, NJ 07054

Carton NDC	Carton Lot	Patch NDC	Patch Lot	Expiration Date
00591-3525-30	1383513B	0591-3525-11	1383513	03/2022

Dear Valued Customer:
Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lot of **Lidocaine Patch 5%** to the **RETAIL** level, which was distributed under the **Actavis Pharma, Inc., label**. This recall is being initiated because a portion of the patches (transdermal pouches) are labeled with an incorrect expiration date of 03/2020 although the outer carton of 30 patches has the correct expiration date of 03/2022. The approved product's indications is for relief of pain associated with post-herpetic neuralgia. The incident does not suggest to have an impact on the safe use of Lidocaine 5% Transdermal Patch although a missed dose would be the most probable end-result if a user does not use a patch. The Health Hazard Assessment concludes the overall risk of harm is considered to be low.

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

Please take the following actions upon receipt of this letter:

- Immediately examine your inventory for the recalled carton lot and/or patch lot.
- Immediately discontinue distribution of and quarantine the lot being recalled.
- Our records indicate we shipped the recalled lot from 05/08/2020 through 06/05/2020.
- **If you have further distributed these 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 the materials to you to process your return. 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 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: 855-547-6375 (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response forms Contact Inmar at: 855-547-6375 or acquire it from clsnetlink.com.
Medical-related Questions or to report an Adverse Event: Contact Teva 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 Teva 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 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.

Teva Pharmaceuticals USA, Inc.

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Lidocaine Patch 5%

STOCK RESPONSE 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 #:_____

Carton NDC	Carton Lot	Patch NDC	Patch Lot	Exp, Date	Number of Full Cartons of 30 to Return	Count of Patches (in Partial Carton) to Return
00591-3525-30	1383513B	0591-3525-11	1383513	03/2022		

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 FAX this form to: 817-868-5362 or 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