URGENT DRUG RECALL

Doxylamine Succinate and Pyridoxine Hydrochloride Delayed-Release Tablets 10 mg/10 mg Initiated 01/18/2021

Teva Pharmaceuticals USA, Inc.

NDC	Bottle Size	Lot	Expiration Date	Quantity Distributed	Distributed
0591-2132-01	100 Count	100025842	08/2023	3,482	10/19/2021 - 11/11/2021
0591-2132-01	100 Count	100028023	08/2023	2,723	11/15/2021 - 12/13/2021

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (Teva USA) is voluntarily recalling the above referenced lots of **Doxylamine Succinate and Pyridoxine Hydrochloride Delayed-Release Tablets 10 mg/10 mg** to the **Retail Level**. The affected product lots were distributed under the label of Actavis Pharma, Inc. Please take the following actions as given below.

This recall has been initiated because assay results are below specification limits for the active ingredient. This drug product is indicated for the treatment of nausea and vomiting from pregnancy in women who have not improved with change in diet or other non-medicine treatments. A decrease in bioavailability and clinical efficacy is the main safety concern that may arise from this quality incident which could potentially cause an exacerbation of nausea and vomiting in pregnant women taking the affected lots. However, the overall risk to patients taking this product are considered to be low. To date, Teva USA has received no adverse event reports or product complaints relative to this quality incident.

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.
- 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 855-319-5710 (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response Forms - Contact Inmar at 855-868-1820 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.

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Initiated 01/18/2021

Teva Pharmaceuticals USA, Inc.

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.

NDC	Bottle Size	Lot	Expiration Date	Quantity of Bottles to Return (Count Partial Bottles as 1)
0591-2132-01	100 Count	100025842	08/2023	
0591-2132-01	100 Count	100028023	08/2023	

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.

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