Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 03/19/2018

Estradiol Vaginal Inserts, USP 10 mcg,

8 inserts/carton (2 x 4 blister packs/carton) and 18 inserts/carton (3 x 6 blister packs/carton)

RECALLED BY:
Teva Pharmaceuticals USA, Inc.
Horsham, PA 19044

Lot Number	Exp. Date	Strength	Carton Size	NDC #
33812545A	12/2018	10 mcg	8 inserts (2 x 4 blister packs)	0093-3223-08
33812546A	12/2018	10 mcg	8 inserts (2 x 4 blister packs)	0093-3223-08
33812774A	12/2018	10 mcg	8 inserts (2 x 4 blister packs)	0093-3223-08
33812775A	01/2019	10 mcg	8 inserts (2 x 4 blister packs)	0093-3223-08
33812776A	05/2019	10 mcg	8 inserts (2 x 4 blister packs)	0093-3223-08
33812777A	05/2019	10 mcg	8 inserts (2 x 4 blister packs)	0093-3223-08
33813786A	07/2019	10 mcg	8 inserts (2 x 4 blister packs)	0093-3223-08
33813868A	07/2019	10 mcg	8 inserts (2 x 4 blister packs)	0093-3223-08
33813974A	09/2019	10 mcg	8 inserts (2 x 4 blister packs)	0093-3223-08
33814058A	09/2019	10 mcg	8 inserts (2 x 4 blister packs)	0093-3223-08
33814113A	10/2019	10 mcg	8 inserts (2 x 4 blister packs)	0093-3223-08
33812547A	01/2019	10 mcg	18 inserts (3 x 6 blister packs)	0093-3223-97
33813361A	01/2019	10 mcg	18 inserts (3 x 6 blister packs)	0093-3223-97
33813676A	01/2019	10 mcg	18 inserts (3 x 6 blister packs)	0093-3223-97

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lots of **Estradiol Vaginal Inserts, USP 10 mcg** distributed under the label, Teva Women's Health Inc., Subsidiary of Teva Pharmaceuticals USA, Inc. This recall is being carried out to the **RETAIL LEVEL** due to product complaints regarding difficulty in dispensing the tablet from the applicator. The consequence of not dispensing that tablet from the applicator is the omission of dose(s) in some patients resulting in reduced efficacy. Based on the available information and for the reasons stated, the use of or exposure to the product may cause temporary or medically reversible adverse events (signs and symptoms of atrophic vaginitis or application site injury) without serious adverse health consequences.

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

- Immediately examine your inventory for the specified lots of Estradiol Vaginal Inserts, USP 10 mcg**.**
- Our records indicate we shipped this product between 07/24/2017 and 02/28/2018.
- Immediately discontinue distribution of the specific lots being recalled.
- **Wholesalers/Distributors/Retailers, if you have further distributed the specified lots, please perform a SUB-RECALL to your retail 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 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 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: 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.
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).
Customer Service-related Questions: Contact Teva Customer Service: 800-545-8800 (Hours of Operation: Live calls received: Monday-Friday, 8:30AM-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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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; if not provided the processing of your form will be delayed*

Address: _____

City: _____ State: _____ Zip: _____

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

Lot Number	Exp. Date	Strength	Carton Size	NDC #	Quantity to Return (Count partial as 1)
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33813676A	01/2019	10 mcg	18 inserts (3 x 6 blister packs)	0093-3223-97	

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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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