



**URGENT DRUG RECALL**  
**Mimvey® (estradiol and norethindrone acetate tablets USP)**

**1 mg/0.5 mg**  
**Initiated 01/07/2022**

**Teva Pharmaceuticals USA, Inc.**

NDC	Lots	Exp. Date	Size (Blister Cards)
0093-5455-28	100018611	03/2022	1 x 28 Tablets
0093-5455-28	100019834	06/2022	1 x 28 Tablets
0093-5455-28	100022226	09/2022	1 x 28 Tablets
0093-5455-28	100024574	01/2023	1 x 28 Tablets
0093-5455-42	100018610	03/2022	5 x 28 Tablets
0093-5455-42	100021521	09/2022	5 x 28 Tablets
0093-5455-42	100024575	01/2023	5 x 28 Tablets

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (Teva USA) is voluntarily recalling the above referenced lots of **Mimvey® (estradiol and norethindrone acetate tablets USP) 1 mg/0.5 mg** to the **Retail Level**. The affected product lots were distributed under the label of Teva Pharmaceuticals USA, Inc. Please take the following actions as given below.

This recall has been initiated because the patient inserts for these lots are missing the "Day of the Week" (DOW) sticker. The DOW sticker can be adhered by the patient to the top of the blister card as a visual aid to help the patient track the day of the week when they started taking the medication, if they started on a day other than a Sunday. This drug product is indicated as a treatment to reduce moderate to severe vasomotor symptoms due to menopause, such as hot flashes and to reduce moderate to severe symptoms of vulvar and vaginal atrophy. It is also indicated for the prevention of postmenopausal osteoporosis. The concern is that the missing DOW sticker could possibly lead to dose omission, which may increase the likelihood of bleeding, spotting, and vasomotor symptoms (hot flashes) due to menopause.

*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 the above referenced lots were shipped from 11/02/2020 – 11/10/2021.
- 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](mailto: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
<b>Product Returns:</b> Contact Inmar at 855-319-5704 (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response Forms - Contact Inmar at 855-319-5704 or acquire forms from <a href="http://clsnetlink.com">clsnetlink.com</a> .
<b>Medical-related Questions or to report an Adverse Event:</b> 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
<b>Product Quality Complaint-related Questions:</b> 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
<b>Customer Service-related Questions:</b> 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
<b>FDA contact information for reporting adverse events/quality complaints:</b> Online at <a href="http://www.fda.gov/medwatch/report.htm">www.fda.gov/medwatch/report.htm</a> or call FDA at 1-800-FDA-1088

Sincerely,

Regulatory Compliance, Teva Pharmaceuticals USA, Inc.



Teva Pharmaceuticals USA, Inc.

**URGENT DRUG RECALL**  
**Mimvey® (estradiol and norethindrone acetate tablets USP)**  
**1 mg/0.5 mg**  
**Initiated 01/07/2022**

**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.

NDC	Lots	Exp. Date	Number of Blister Cards to Return
0093-5455-28	100018611	03/2022	
0093-5455-28	100019834	06/2022	
0093-5455-28	100022226	09/2022	
0093-5455-28	100024574	01/2023	
0093-5455-42	100018610	03/2022	
0093-5455-42	100021521	09/2022	
0093-5455-42	100024575	01/2023	

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](mailto: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