URGENT DRUG RECALL

Tri-Lo-Sprintec® 28 DAY REGIMEN

(norgestimate and ethinyl estradiol tablets USP– triphasic regimen)

March 07, 2024

Teva Pharmaceuticals USA, Inc.

Lot	Exp. Date	Size	NDC Carton	NDC Blister Card
100038111	07 2024	3 Blister Cards, 28 Tablets Each	0093-2140-62	0093-2140-28
100039678	04 2024	3 Blister Cards, 28 Tablets Each	0093-2140-62	0093-2140-28
100042277	07 2024	3 Blister Cards, 28 Tablets Each	0093-2140-62	0093-2140-28

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. (TEVA USA) is initiating a voluntary nationwide recall of the above referenced drug products to the **RETAIL LEVEL.** The products in this recall were distributed to TEVA USA direct customers under the Teva Pharmaceuticals USA, Inc. label**.** The reason for the recall is out-of-specification (OOS) dissolution results have been obtained for these specified lots. A Teva USA Health Hazard Assessment determined that the main health consequence that could arise from this OOS dissolution result is decreased efficacy of the product, possibly leading to an unexpected or unplanned pregnancy. However, because the active substances norgestimate and ethinyl estradiol are rapidly absorbed following oral administration, a slight deviation in dissolution will not have a significant clinical impact on the patients taking this medicine, especially those who have already reached steady-state concentration. Therefore, the exposure to the product of concern is not expected to lead to adverse health consequences outside of the known safety profile of the drug.

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 specified lots being recalled**.**
- Immediately discontinue distribution of the specific lots being recalled.
- TEVA's records indicate that the specified lots were commercially distributed/shipped to its direct customers from 2/13/2023 through 11/8/2023.
- **If you have further distributed the recall lots, please perform a SUB-RECALL to your sub-accounts using this Recall Notification and Business Reply Form (BRF) as a basis for your recall notification.**
- Promptly complete the attached Recall BRF, even if you have **no** product to return, and return the completed Recall BRF to Inmar, Attn: Recall Coordinator by any one of these means:

  MAIL: Inmar, One West Fourth Street, Suite 500, Winston Salem, NC 27101
  EMAIL: **rxrecalls@inmar.com.**
  FAX: 817-868-5362.

After receipt of your Recall BRF, Inmar will send labels for your Return Goods Authorization (RGA) and shipping of your product return. Appropriate credit for your product returns, plus expenses for handling and shipping, will be issued after receipt of said product with your RGA. All recalled product returned without a RGA will 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 866-659-8066 (Hours of Operation: M – F, 9.00 am to 5.00 pm Eastern Time) for Recall Business Stock Response forms or acquire 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, 8:30 AM - 5:00 PM Eastern Time; Voicemail: 24 hrs./day, 7 days/week or by email at druginfo@tevapharm.com
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 or by email at QAS@tevapharm.com
Customer Service-related Questions: Contact Teva Customer Service: 888-838-2872, option 3, then option 2 Live calls received: M - F, 9:00 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.

URGENT DRUG RECALL
Tri-Lo-Sprintec® 28 DAY REGIMEN
(norgestimate and ethinyl estradiol tablets USP– triphasic regimen)
March 07, 2024

Teva Pharmaceuticals USA, Inc.

Date Form Completed _____

RECALL BUSINESS REPLY FORM

Promptly return your completed Business Reply Form (BRF) by any one of these means to Inmar, Attn: Recall Coordinator
MAIL: Inmar, 1 W 4th St., Winston Salem, NC 27101 EMAIL: rxrecalls@inmar.com FAX: 817-868-5362

Section 1 – Customer Information

This Stock Response is for (Check One): ☐ **Teva Direct Account** ☐ **Non-Direct Customer**

Customer/Store Name:	Address (Street/City/State/Zip)
*DEA #: ***DEA # is required; in order to process your form.***	*Debit Memo #
Contact Name (please print):	Telephone #:

Please mark your answer - I have checked my stock and):

☐ I ***do*** have stock of the recalled item(s) **(complete section 2) OR** ☐ I **do not** have stock of the recalled item(s).

Teva Direct Accounts
Does your response include **all** your DC locations? ☐ YES ☐ NO

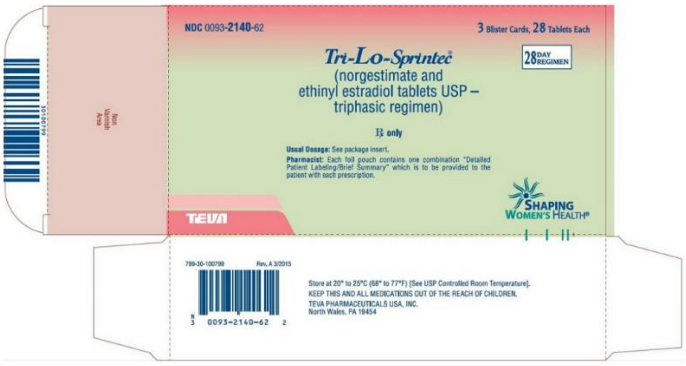
Non-Direct Customer
The product(s) in this recall were purchased from: _____ / Location: _____

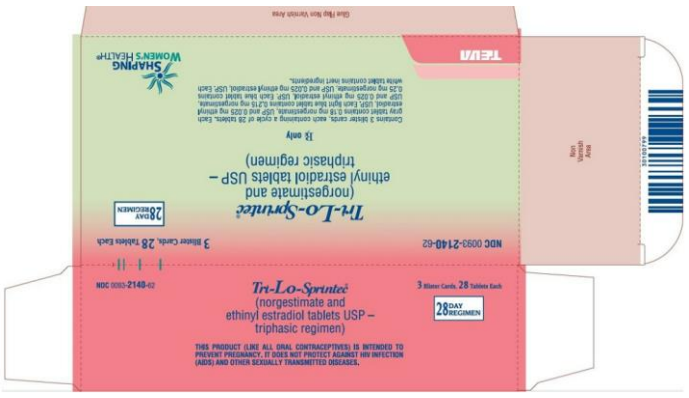
Section 2– Wholesalers/Distributors/Retailers – Quantity of Product to Return

Enter the information of the recalled product(s) to be returned in the table below. If additional space is needed, please make copies of this form.

Lot	Quanty of product to return. (count partial cartons as 1)
100038111	
100039678	
100042277	

Images Shown Have Not Been Reproduced to Scale of Actual Product Cartons





Inmar/MedTurn Use Only:				
Scan	Labels	Store	Kit	D.B