

Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 11/20/17

Amethyst™

(Levonorgestrel and Ethinyl Estradiol Tablets USP, 90mcg/20mcg) 28 Tablets/Blister Pack

RECALLED BY:

Teva Pharmaceuticals USA, Inc.

Horsham, PA 19044

Lot #	Exp. Date	Strength	Pack Size	NDC
544637A	05/2019	90mcg/20mcg	28 tablets/blister pack	52544-295-28

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling the above lot of **Amethyst™ (Levonorgestrel and Ethinyl Estradiol Tablets USP, 90mcg/20mcg)** distributed under the **Actavis Pharma Inc. label**. This recall is being carried out to the **RETAIL LEVEL** due to an incorrect description printed on the blister foil and package insert, stating “TABLETS IN WEEK 4 ARE INACTIVE”. However, each blister foil unit contains 28 active tablets. No adverse health consequences are expected if patients follow the correct instructions.

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

- Examine your inventory immediately for the specified lot of **Amethyst™ (Levonorgestrel and Ethinyl Estradiol Tablets USP, 90mcg/20mcg)**.
- Our records indicate we shipped this product between October 02, 2017 and October 17, 2017.
- Immediately discontinue distribution of the specific lot being recalled.
- **Wholesalers/Distributors/Retailers, if you have further distributed the specific lot, 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 your 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.

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).

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).

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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Amethyst™

**(Levonorgestrel and Ethinyl Estradiol Tablets USP, 90mcg/20mcg)
28 Tablets/Blister Pack**

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 #	Exp. Date	Strength	Pack Size	NDC	Quantity to Return (Count partials as 1)
544637A	05/2019	90mcg/20mcg	28 tablets/blister pack	52544-295-28	

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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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

**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
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