Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – RETAIL LEVEL - INITIATED 02/20/2020

Mesalamine Delayed-Release Tablets, USP 1.2 g

RECALLED BY:
Teva Pharmaceuticals USA, Inc.
North Wales, PA 19454

Lot #	Exp. Date	Strength	Bottle Size	NDC
1342500A	10/2020	1.2 g	120 Tablets	0591-2245-22

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling to the RETAIL LEVEL the above mentioned lot of **Mesalamine Delayed-Release Tablets, USP 1.2 g** that was distributed under the **Actavis Pharma Inc.**, label**.** This recall is being initiated due to an out of specification dissolution result observed during stability testing. The other analytical tests for the lot met specifications. Based on the health hazard assessment, use of the product being recalled may cause adverse health consequences such as reduced treatment efficacy especially in patients experiencing flare-ups of the disease; nevertheless, the likelihood is remote by taking into consideration the close medical supervision of patients with ulcerative colitis.

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

- Immediately examine your inventory for Lot 1342500A of **Mesalamine Delayed-Release Tablets, USP 1.2 g.**
- Our records indicate we shipped Lot 1342500A from October 11, 2019 through October 16, 2019.
- Immediately discontinue distribution of Lot 1342500A being recalled.
- **Wholesalers/Distributors/Retailers, if you have further distributed Lot 1342500A, please perform a SUB-RECALL to your [retail/wholesale] 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, shipping label. 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: 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 3, then, option 3 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 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.

Teva Pharmaceuticals USA, Inc.

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Mesalamine Delayed-Release Tablets, USP 1.2 g

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; in order to process your form.*

Address: _____

City: _____ State: _____ Zip: _____

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

Lot #	Exp. Date	NDC	Quantity to Return (Count Partial Bottles as 1)
1342500A	10/2020	0591-2245-22	

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: _____

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