URGENT DRUG RECALL

Mesalamine Delayed-Release Tablets, USP 1.2 g

INITIATED 10/28/2020

teva

NOV 0 3 2020

Teva Pharmaceuticals USA, Inc.

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. is voluntarily recalling 19 lots of Mesalamine Delayed-Release Tablets, USP 1.2 g to the RETAIL LEVEL that were distributed under the Actavis Pharma Inc., label. Refer to Attachment I of this letter for the list of 19 lots being recalled.

This recall is being initiated because out of specification dissolution results were obtained during stability testing of lot 1395725A. Specifically, the drug release result is below specification limits. The other specified lots may potentially be impacted by this OOS. Based on the health hazard assessment, use of product impacted by reduced drug release may result in reduced treatment efficacy although the likelihood of adverse events occurring is remote.

This recall is being made with the knowledge of the Food and Drug Administration.

Please perform the following activities that are necessary for this recall:

- Immediately examine your inventory for the specified lots of **Mesalamine Delayed-Release Tablets, USP 1.2 g.**
- Immediately discontinue distribution of the product lots affected by this recall.
- Our records indicate Teva USA shipped the specified lots to its customers from April 11, 2019 through July 13 2020.
- **If you have further distributed these lots, please perform a SUB-RECALL to your accounts. Use this Recall Notification and Stock Response Form as a basis for your SUB-RECALL letter.**
- 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: 877-296-2607. (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response Forms - Contact Inmar at: 877-296-2607 or acquire forms 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 4 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 3 then, 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.

Attachment I – Recall Product Lots				
NDC	**Lot #**	**Exp. Date**	**Strength**	**Bottle Size**
0591-2245-22	1342498A	12/2020	1.2 g	120
0591-2245-22	1342499A	01/2021	1.2 g	120
0591-2245-22	1354638A	03/2021	1.2 g	120
0591-2245-22	1354639A	05/2021	1.2 g	120
0591-2245-22	1358274A	05/2021	1.2 g	120
0591-2245-22	1358448A	05/2021	1.2 g	120
0591-2245-22	1364618A	05/2021	1.2 g	120
0591-2245-22	1366195A	06/2021	1.2 g	120
0591-2245-22	1369884A	05/2021	1.2 g	120
0591-2245-22	1369885A	06/2021	1.2 g	120
0591-2245-22	1373570A	06/2021	1.2 g	120
0591-2245-22	1373571A	07/2021	1.2 g	120
0591-2245-22	1388571A	01/2022	1.2 g	120
0591-2245-22	1395725A	04/2022	1.2 g	120
0591-2245-22	1396585A	04/2022	1.2 g	120
0591-2245-22	1397550A	04/2022	1.2 g	120
0591-2245-22	1399389A	04/2022	1.2 g	120
0591-2245-22	1403885A	06/2022	1.2 g	120
0591-2245-22	1403886A	06/2022	1.2 g	120

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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** 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 #: _____

Refer to Attachment I of the recall letter for the list of lots being recalled

NDC	Lot #	Exp. Date	Quantity to Return (Count Partial Bottles as 1)

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 return this form by FAX to: 817-868-5362 or by 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