

Teva Pharmaceuticals USA, Inc.

URGENT DRUG RECALL – CONSUMER LEVEL - INITIATED 06/02/2020

Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 750 mg

RECALLED BY:

**Teva Pharmaceuticals USA, Inc.
Parsippany, NJ 07054**

Lot #	Exp. Date	Strength	Bottle Count	NDC
1329548A	06/2020	500 mg	100 Count	62037-571-01
1338302M	10/2020	500 mg	100 Count	62037-571-01
1348968M	10/2020	500 mg	100 Count	62037-571-01
1348969M	11/2020	500 mg	100 Count	62037-571-01
1348970M	10/2020	500 mg	100 Count	62037-571-01
1376339M	09/2021	500 mg	100 Count	62037-571-01
1323460M	06/2020	500 mg	1000 Count	62037-571-10
1330919M	06/2020	500 mg	1000 Count	62037-571-10
1338300A	10/2020	500 mg	1000 Count	62037-571-10
1341135M	12/2020	500 mg	1000 Count	62037-571-10
1391828M	11/2021	500 mg	1000 Count	62037-571-10
1333338M	08/2020	750 mg	100 Count	62037-577-01
1333339A	08/2020	750 mg	100 Count	62037-577-01
1354471A	02/2021	750 mg	1000 Count	62037-577-10

Dear Valued Customer:

Teva Pharmaceuticals USA, Inc. ("Teva") is voluntarily recalling the above lots of Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 750 mg, 100 and 1000 count bottles that was distributed in United States under the Actavis Pharma, Inc. label to the consumer level. The lots are being recalled due to detection of N-Nitrosodimethylamine (NDMA) levels in excess of the Acceptable Daily Intake Limit (ADI).

NDMA is classified as a probable human carcinogen based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables. Metformin is indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus. Patients taking Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 750 mg, are advised to continue taking their medication and contact their health care professional who can prescribe a replacement. According to the US Food & Drug Administration (the "FDA"), it could be dangerous for patients with type 2 diabetes to stop taking their metformin without first talking to their health care professionals. The FDA has advised that patients should continue taking metformin tablets even after recalls occur, until they consult with their health care professional who can prescribe a replacement.

This recall is being made with the knowledge of the FDA.

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

- Immediately examine your inventory for the specified lots of Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 750 mg.
- Our records indicate we shipped this product from **01/08/2019** through **05/27/2020**.
- Immediately discontinue distribution of product lots being recalled.
- **Wholesalers/Distributors/Retailers**, if you have further distributed the lots, please perform a SUB-RECALL to your Retail / Direct Accounts (sub-accounts). Please use this Recall Notification and Stock Response Form as a basis for your SUB-RECALL letter.
- **An information letter for Consumers/Patients/Caregivers concerning this voluntary recall is included with this notification. Please provide the letter to your sub-accounts to give to their Consumers/Patients/Caregivers.**
- Even if there is **no** recalled 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: tevarecalls@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 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.

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CONTACT INFORMATION AND CREDIT	
<u>Product Returns:</u>	Contact Inmar at: 855-532-1850 (Hours of Operation: 9 am to 5 pm Eastern Time) Recall Stock Response forms Contact Inmar at 855-532-1850 or acquire it from clsnetlink.com.
<u>Medical-related Questions or to report an Adverse Event:</u>	Contact Medical Information at: 888-838-2872, option 3, then option 4 Live calls received: Monday-Friday, 9:00 am - 5:00 pm Eastern Time; Voicemail: 24 hrs./day, 7 days/week
<u>Product Quality Complaint-related Questions:</u>	Contact Quality Assurance Services: 888-838-2872, option 3, then, option 3 (Hours of Operation: Live calls received: Monday-Friday, 9:00 am - 5:00 pm Eastern Time; Voicemail: 24 hrs./day, 7 days/week).
<u>Customer Service-related Questions:</u>	Contact Teva Customer Service: 888-838-2872, option 2 (Hours of Operation: Live calls received: Monday-Friday, 8:30 am - 5:00 pm Eastern Time; Voicemail: 24 hrs./day, 7 days/week).
<u>FDA contact information for reporting adverse events/quality complaints:</u>	Online at www.fda.gov/medwatch/report.htm or call FDA at 1-800-FDA-1088

Sincerely,
Regulatory Compliance, Teva Pharmaceuticals USA, Inc.

Attachment: Stock Response Form; Letter - Information for Consumers/Patients/Caregivers

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STOCK RESPONSE FORM

Please fill out completely

Date: _____

DIRECT CUSTOMERS ONLY: Does this response include **all** your 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 #: _____

NDC	Product Description	Lot #	Expiration	Quantity to Return (Count partial as 1)
62037-571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100	1329548A	06/2020	
62037-571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100	1338302M	10/2020	
62037-571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100	1348968M	10/2020	
62037-571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100	1348969M	11/2020	
62037-571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100	1348970M	10/2020	
62037-571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100	1376339M	09/2021	
62037-571-10	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 1000	1323460M	06/2020	
62037-571-10	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 1000	1330919M	06/2020	
62037-571-10	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 1000	1338300A	10/2020	
62037-571-10	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 1000	1341135M	12/2020	
62037-571-10	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 1000	1391828M	11/2021	
62037-577-01	Metformin Hydrochloride Extended-Release Tablets, USP 750 mg 100	1333338M	08/2020	
62037-577-01	Metformin Hydrochloride Extended-Release Tablets, USP 750 mg 100	1333339A	08/2020	
62037-577-10	Metformin Hydrochloride Extended-Release Tablets, USP 750 mg 1000	1354471A	02/2021	

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: _____

Inmar/MedTurn Use Only:

Scan	Labels	Store	Kit	D.B
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