DOCTORS HEALTHCARE PLANS, INC.

FDA Drug Recall

Teva Pharmaceuticals Initiates Voluntary Nationwide Recall of Metformin ER Tablets 500 mg and 750 mg Due to Detection of NDMA

June 2, 2020

Teva Pharmaceuticals USA, Inc. is voluntarily recalling fourteen (14) lots of Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 750 mg, 100 and 1000 count bottles, in the United States to the consumer-level due to the detection of N-Nitrosodimethylamine (NDMA) levels in excess of the Acceptable Daily Intake Limit (ADI).

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) 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 Hydrochloride is indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus. The lots being recalled are packaged under the Actavis Pharma, Inc. label and are contained in the table below. They were distributed nationwide in the USA as retail bottles of 100 tablets and 1000 tablets to Teva's direct customers between January 8, 2019 and May 27, 2020.

The affected Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 750 mg, being recalled are described as:

- Metformin Hydrochloride Extended-Release Tablets, USP 500 mg, white to off-white capsule shaped tablets, debossed with an Andrx logo with "571"on one side and "500" on the opposite side.
- Metformin Hydrochloride Extended-Release Tablets, USP 750 mg, light yellow capsule shaped tablets, debossed with an Andrx logo with "577" on one side and "750" on the opposite side.

NDC	Product Description	Lot Number	Expiration
62037-571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100 Count	1329548A	06/2020
62037-571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100 Count	1338302M	10/2020

NDC	Product Description	Lot Number	Expiration
62037-571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100 Count	1348968M	10/2020
62037-571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100 Count	1348969M	11/2020
62037-571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100 Count	1348970M	10/2020
62037-571-01	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 100 Count	1376339M	09/2021
62037-571-10	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 1000 Count	1323460M	06/2020
62037-571-10	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 1000 Count	1330919M	06/2020
62037-571-10	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 1000 Count	1338300A	10/2020
62037-571-10	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 1000 Count	1341135M	12/2020
62037-571-10	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg 1000 Count	1391828M	11/2021
62037-577-01	Metformin Hydrochloride Extended-Release Tablets, USP 750 mg 100 Count	1333338M	08/2020
62037-577-01	Metformin Hydrochloride Extended-Release Tablets, USP 750 mg 100 Count	1333339A	08/2020
62037-577-10	Metformin Hydrochloride Extended-Release Tablets, USP 750 mg 1000 Count	1354471A	02/2021

Teva is notifying its distributors and customers affected by this recall via FedEx overnight mailing. Patients taking Metformin Hydrochloride Extended-Release Tablets, USP 500 mg and 750 mg, are advised to continue taking their medication and contact their pharmacist, physician, or medical provider for advice regarding an alternative treatment. According to the US Food & Drug Administration, It could be dangerous for patients with this serious condition to stop taking their metformin without first talking to their health care professionals. Please visit the agency’s website

for more information at https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin.

Customers and patients with medical-related questions, who wish to report an adverse event, or quality issues about the Teva products being recalled should contact Teva Medical Information by phone at: 888-838-2872, option 3, then, option 4. Live calls are received Monday-Friday, 9:00 am to 5:00 pm Eastern Time with voicemail available 24 hours/day, 7 days/week or by email at druginfo@tevapharm.com.

Patients wishing to return product may contact Teva's product recall processor to obtain instructions and a return kit for returning their medication:

- Contact Inmar at 1-855-532-1850 (Hours of Operation: 9 am to 5 pm Eastern Time, Monday – Friday) or email Inmar at: tevarecalls@inmar.com.
- Inmar will provide the materials needed to return their medication and instructions for reimbursement.
Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Patient safety and product quality are critical to Teva. Teva will continue to partner with, and regularly update, all relevant regulatory authorities as relevant information becomes available.

Company Contact Information

Consumers:

Teva's Medical Information

888-838-2872

druginfo@tevapharm.com

Media:

Kelley Dougherty, Eric Rubin

973-832-2819, 862-221-7151

Product Photos

NDC 62037-**571**-01

500 mg

Metformin Hydrochloride

Extended-Release Tablets, USP

571

Actavis

100 Tablets
Rx Only

Each Extended-Release Tablet Contains:
Metformin Hydrochloride, USP ..... 500 mg

Dispense in a light-resistant container.

Usual Dosage: See enclosed package insert for dosage information.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Manufactured by:
Watson Pharma Private Limited
Verna, Salcette Goa 403 722 INDIA

Distributed by:
Actavis Pharma, Inc.
Parsippany, NJ 07054 USA

Rev. 02/16

231866

LOT/EXP. BELOW

SAMPLE

N 3 62037 57101 5

-

NDC 62037-**577**-01

750 mg

Metformin Hydrochloride

Extended-Release Tablets, USP

577

Actavis

100 Tablets
Rx Only

Each Extended-Release Tablet Contains:
Metformin Hydrochloride, USP ..... 750 mg

Dispense in a light-resistant container.

Usual Dosage: See enclosed package insert for dosage information.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Manufactured by:
Watson Pharma Private Limited
Verna, Salcette Goa 403 722 INDIA

Distributed by:
Actavis Pharma, Inc.
Parsippany, NJ 07054 USA

Rev. 02/16

231868

LOT/EXP. BELOW

SAMPLE

N 3 62037 57701 7

-

NDC 62037-**571**-10

500 mg

Metformin Hydrochloride

Extended-Release Tablets, USP

571

Actavis

1,000 Tablets
Rx Only

Each Extended-Release Tablet Contains:
Metformin Hydrochloride, USP ..... 500 mg

Dispense in a light-resistant container.

Usual Dosage: See enclosed package insert for dosage information.

Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature.]

Manufactured by:
Watson Pharma Private Limited
Verna, Salcette Goa 403 722 INDIA

Distributed by:
Actavis Pharma, Inc.
Parsippany, NJ 07054 USA

Rev. 02/16

231867

LOT/EXP. BELOW

SAMPLE

N 3 62037 57110 7

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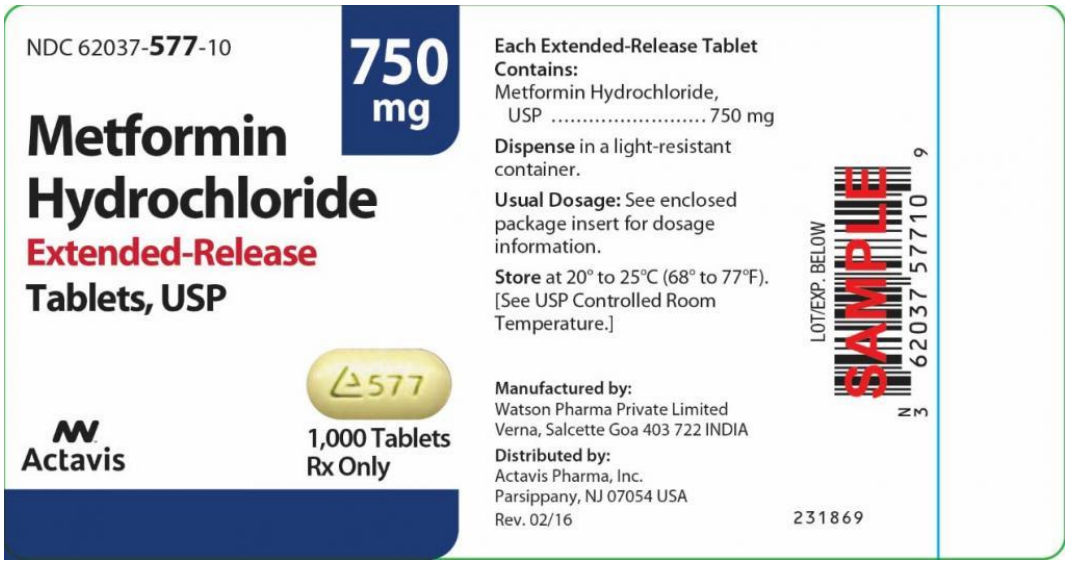

Source: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/teva-pharmaceuticals-usa-inc-initiates-voluntary-nationwide-recall-metformin-hydrochloride-extended?utm_campaign=Teva%20Pharmaceuticals%20USA%2C%20Inc.%20Initiates%20Voluntary%20Nationwide%20Recall%20of%20Metformin%20Hydrochloride&utm_medium=email&utm_source=Eloqua