

COMPANY ANNOUNCEMENT

Granules Pharmaceuticals, Inc. Issues Voluntary Nationwide Recall of Metformin Hydrochloride Extended-Release Tablets USP, 750 mg Due to the Detection of N-Nitrosodimethylamine (NDMA) Impurity

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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Summary

Company Announcement Date:

July 03, 2020

FDA Publish Date:

July 06, 2020

Product Type:

Drugs

Reason for Announcement:

N-Nitrosodimethylamine (NDMA)

Company Name:

Baxter International Inc.

Brand Name:

Granules

Product Description:

Metformin Hydrochloride Extended-Release Tablets USP, 750 mg

Company Announcement

Granules Pharmaceuticals, Inc., Chantilly, VA is voluntarily recalling twelve (12) lots of Metformin Hydrochloride Extended-Release Tablets USP, 750 mg, 100 and 500 count bottles within expiry to the consumer level due to the detection of NNitrosodimethylamine (NDMA) levels above the Acceptable Daily Intake Limit.

Granules’ test results showed NDMA levels above the FDA acceptable limit in **one (1) out of the twelve (12) batches distributed to the US market**. All other batches continue to remain within the specifications. Out of abundance of caution Granules Pharmaceuticals, Inc. has decided to voluntarily recall all twelve (12) of the distributed lots within expiry of Metformin Hydrochloride Extended-Release Tablets USP, 750 mg from the market.

Granules Pharmaceuticals, Inc. has not received any reports of adverse events that have been confirmed to be directly related to this recall as of the date of this letter.

Granules Metformin Hydrochloride Immediate-Release Tablets USP, 500 mg, 850 mg & 1000 mg and Metformin Hydrochloride Extended-Release Tablets USP, 500 mg are not affected by this recall.

Risk Statement: 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 Extended-Release Tablets USP, 750 mg are indicated as an adjunct to diet and exercise to improve blood sugar control in adults with type 2 diabetes mellitus. The Metformin Hydrochloride Extended-Release Tablets USP, 750 mg lots subject to the recall is identified in the table below.

Metformin Hydrochloride Extended-Release Tablets USP, 750 mg

NDC	Bottle Count	Lot/Expiration
70010-492-01	100 count bottles	4920003A/May-21 4920004A/Jun-21 4920005A/Jun-21 4920009A/Nov-21 4920010A/May-22 4920011A/Jun-22 4920012A/Jun-22 4920013A/Jul-22 4920014A/Jul-22 4920015A/Aug-22 4920016A/Jan-23
70010-492-05	500 count bottles	4920005B/Jun-21

The affected Metformin Hydrochloride Extended-Release Tablets USP, 750 mg, lots were distributed nationwide in the USA directly to Distributors, and Retailers. Granules Pharmaceuticals, Inc. is in the process of notifying its distributors and customers affected by this recall via mail (FedEx standard overnight) by mailing a recall notification letter and is arranging for return of the entire recalled product. Anyone with an existing inventory of the product should quarantine the recalled lots immediately.

Customers and patients with questions regarding this recall or wishing to return product may contact Inmar Pharmaceutical Services product recall processor to obtain instructions and a return kit for returning their medication:

- Contact Inmar at 888-985-9117 (Hours of Operation: 9 am to 5 pm Eastern Time, Monday – Friday) or email Inmar at: rxrecalls@inmar.com (<mailto:rxrecalls@inmar.com>).
- Inmar will provide the materials needed to return their medication and instructions for reimbursement.

If you would like to report any adverse reactions or quality problems experienced with the use of this product you may contact Granules Drug Safety by phone at 1-877-7703183 Monday - Friday, 8:00 am EST to 8:00 pm EST, or via e-mail at drugs.safety@granulesindia.com (<mailto:drugs.safety@granulesindia.com>).

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 (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>)
- Regular Mail or Fax: Download form (</safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>) 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.

Company Contact Information

Consumers:

Inmar, Pharmaceutical Services

☎ 888-985-9117

✉ rxrecalls@inmar.com (<mailto:rxrecalls@inmar.com>)

Media:

Mary D Villalona, Director, Quality

☎ 571-665-2914

✉ mary.villalona@granulespharma.com (<mailto:mary.villalona@granulespharma.com>)

Product Photos

NDC 70010-492-01

**Metformin Hydrochloride
Extended-Release
Tablets, USP**

750 mg

100 Tablets

Rx only

Each tablet contains 750 mg of metformin hydrochloride, USP.
See enclosed package insert for dosage information.
Warning: Keep out of the reach of children.
Store at 20° to 25° C (68° to 77° F); excursions permitted within 15° to 30° C (59° to 86° F).
[See USP Controlled Room Temperature.]
Dispense in light-resistant container.

Manufactured for:
Granules Pharmaceuticals Inc.,
Chantilly, VA 20151

Manufactured by:
Granules India Limited
Hyderabad – 500 081, India.
MADE IN INDIA
R05/18
M. L. No.: 37/RR/API/2003/F/R

Prompt LOT: & EXP: will be printed online along with variable data.

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NDC 70010-492-05

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Extended-Release
Tablets, USP**

750 mg

500 Tablets

Rx only

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