RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Metformin Hydrochloride ER Tablets Recall Alert

Date of Notice: 07/03/2020

Brief Description of Recall Alert

Granules Pharmaceuticals, Inc. is voluntarily recalling twelve (12) lots of metformin hydrochloride extended-release tablets USP, 750 mg due to the detection of N-Nitrosodimethylamine (NDMA) levels above acceptable limits.

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' metformin hydrochloride immediate-release tablets USP, 500 mg, 850 mg and 1000 mg and metformin hydrochloride extended-release tablets USP, 500 mg are not affected by this recall.

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 found in water and foods, including meats, dairy products, and vegetables.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
metformin HCl ER tablets, USP 750 mg	70010-492-01	4920003A	05/2021
metformin HCl ER tablets, USP 750 mg	70010-492-01	4920004A	06/2021
metformin HCl ER tablets, USP 750 mg	70010-492-01	4920005A	
metformin HCl ER tablets, USP 750 mg	70010-492-01	4920009A	11/2021
metformin HCl ER tablets, USP 750 mg	70010-492-01	4920010A	05/2022
metformin HCl ER tablets, USP 750 mg	70010-492-01	4920011A	06/2022
metformin HCl ER tablets, USP 750 mg	70010-492-01	4920012A	
metformin HCl ER tablets, USP 750 mg	70010-492-01	4920013A	07/2022
metformin HCl ER tablets, USP 750 mg	70010-492-01	4920014A	
metformin HCl ER tablets, USP 750 mg	70010-492-01	4920015A	08/2022
metformin HCl ER tablets, USP 750 mg	70010-492-01	4920016A	01/2023

metformin HCl ER tablets, USP 750 mg	70010-492-05	4920005B	06/2021

Prescriber Information

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.

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 1-877-770-3183 Monday - Friday, 8:00 am EST to 8:00 pm EST, or via e-mail at drugs.safety@granulesindia.com.

Adverse reactions or quality problems experienced with the use of this drug 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

Member Information

Members 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 drug:

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.

Inmar will provide the materials needed to return the drug and instructions for reimbursement.

RxAdvance Response

Members should continue taking metformin until a doctor or pharmacist provides a replacement drug (if needed) or a different treatment option. RxAdvance is in the process of contacting members and prescribers to advise them of this recall.