July 7, 2020 COM-2020-049

RECALL NOTIFICATION

FDA PUBLICATION DATE: July 6, 2020

DRUG NAME:

Metformin Hydrochloride Extended-Release Tablets USP, 750 mg

COMPANY: Granules Pharmaceuticals, Inc.

REASON: Detection of N-Nitrosodimethylamine (NDMA)

Dear provider of pharmaceutical services,

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate you with the latest up-to-date information on drug recalls. It is for this reason that we are notifying you that on July 6, 2020 the US Food and Drug Administration (FDA) published a drug recall for the following product(s):

Affected product	NDC	Bottle count	Lot/Expiration
Metformin Hydrochloride Extended-Release Tablets USP, 750 mg	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

Note: 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.

Pharmacy required action(s):

- Identify if the product is inventory and immediately stop using and dispensing it.
- Contact all members that in the previous 90 days received the recalled medication.
- Advise patients to contact their physician if they have experienced any problems that may be related to taking or using this product.

2 Street 1, Suite 500 Guaynabo, PR 00968 | Tel. 787.522.5252 | Fax 1.866.912.2830 | www.pharmpix.com

Contact information:

- Inmar Pharmaceutical Services product recall processor:
  - Phone: 888-985-9117 (Hours of Operation: 9 am to 5 pm Eastern Time, Monday – Friday)
  - Email: rxrecalls@inmar.com

Remember you can report adverse events related to this or any other drug product at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download FDA Form 3500 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.

Additional information can be found at: MedWatch: The FDA Safety Information and Adverse Event Reporting Program.

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

- 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. U.S. Food and Drug Administration. (2020). Retrieved 7 July 2020, from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/granules-pharmaceuticals-inc-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended.