



## Granules Pharmaceuticals – Recall of metformin extended-release (ER)

- On July 6, 2020, [Granules Pharmaceuticals announced](#) a voluntary, consumer-level recall of all lots of [metformin ER](#) tablets due to the detection of N-nitrosodimethylamine (NDMA) levels in excess of acceptable FDA levels.
- 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.
- Granules Pharmaceuticals began shipping this product on March 21, 2019.

| Product Description  | NDC#                          | Lot#  |
|--|-------------------------------|---|
| Metformin Hydrochloride<br>Extended-Release 750 mg tablets | 70010-492-01;<br>70010-492-05 | 4920003A, 4920004A,<br>4920005A, 4920005B,<br>4920009A, 4920010A,<br>4920011A, 4920012A,<br>4920013A, 4920014A,<br>4920015A, 4920016A |

- Metformin ER tablets are indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus.
- Patients who have the recalled metformin ER should continue taking it and contact their physician or healthcare provider to prescribe a replacement.
- Health care professionals should continue to prescribe metformin when clinically appropriate. FDA testing has not shown NDMA in immediate release (IR) metformin products (the most commonly prescribed type of metformin).
- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.
- The FDA continues to evaluate the safety of metformin and will provide more information as it becomes available. Updates can be found [here](#).
- Contact Inmar (appointed company for Granules) by phone at **1-888-985-9117** or by email at [recalls@inmar.com](mailto:recalls@inmar.com) for further information regarding this recall.



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