

## Lupin - Recall of metformin extended-release

- On June 10, 2020, <u>Lupin announced</u> a voluntary, consumer-level recall of one lot of <u>metformin</u> extended-release (ER) tablets due to the detection of N-nitrosodimethylamine (NDMA) impurities.
- 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.

Product Description	NDC#	Lot# (Expiration Date)
Metformin ER 500 mg tablets	68180-336-07	G901203 (12/2020)

- 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 until a doctor or pharmacist gives them a replacement or a different treatment option.
- 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 <a href="here">here</a>. Commonly asked questions about NDMA impurities in metformin products can be found <a href="here">here</a>.
- Contact Inmar by phone at 1-855-532-1856 for more information about this recall.



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