Lupin – Recall of metformin extended-release (ER)

- On July 8, 2020, Lupin Pharmaceuticals announced a voluntary, consumer-level recall of all lots of metformin ER 500 mg and 1000 mg tablets due to the detection of N-nitrosodimethylamine (NDMA) levels in excess of the acceptable daily intake limit.
    - The FDA recommended the recall certain lots of Lupin's metformin ER due to NDMA levels; however, out of an abundance of caution, Lupin decided to recall all lots of metformin ER.
- 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.
- The recalled lots were distributed nationwide between November 5, 2018 and May 27, 2020.

Product Description	NDC#	Lot#
Metformin Hydrochloride Extended-Release 500 mg tablets	68180-338-01; 68180-336-07	All
Metformin Hydrochloride Extended-Release 1000 mg tablets	68180-339-09; 68180-337-07	All

- 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 Rx Solutions by phone at **1-855-532-1856** for further information regarding this recall.