Teva – Recall of metformin extended-release (ER)

- On June 2, 2020, Teva announced a voluntary, consumer-level recall of 14 lots of metformin ER tablets due to the detection of N-nitrosodimethylamine (NDMA) levels in excess of the acceptable daily intake limit.
- 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 packaged under the Actavis Pharma label and distributed in the U.S. between January 8, 2019 and May 27, 2020.

Product Description	NDC#	Lot# (Expiration Date)
Metformin Hydrochloride Extended-Release 500 mg tablets	62037-571-01	1329548A (06/2020); 1338302M (10/2020); 1348968M (10/2020); 1348969M (11/2020); 1348970M (10/2020); 1376339M (09/2021)
	62037-571-10	1323460M (06/2020); 1330919M (06/2020); 1338300A (10/2020); 1341135M (12/2020); 1391828M (11/2021)
Metformin Hydrochloride Extended-Release 750 mg tablets	62037-577-01	1333338M (08/2020); 1333339A (08/2020)
	62037-577-10	1354471A (02/2021)

- 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.

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- Contact Teva Medical Information by phone at **1-888-838-2872** or by email at **druginfo@tevapharm.com** for further information regarding this recall.