OPTUMRx®

Apotex, AvKare, and Marksans – Recalls of metformin extended-release

- On June 5, 2020, AvKare, Apotex, and Marksans Pharma announced voluntary, consumer-level recalls of metformin extended-release (ER) tablets due to the detection of N-nitrosodimethylamine (NDMA) impurities.
    - Apotex is expanding the previously announced retail level recall of metformin ER tablets that was initiated on May 29, 2020 to the consumer level.
    - Apotex stopped selling metformin ER to the U.S. in February 2019. There only remains limited product on the market.
    - Avkare is recalling all unexpired lots of metformin ER 500 mg and 750 mg tablets.
    - Marksans is recalling one lot of metformin ER 500 mg tablets.
- 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.

Manufacturer	Manufacturer Contact Information	Product Description	NDC#	Lot# (Expiration Date)
Apotex	1-800-706-5575; UScustomerservice@Apotex.com	Metformin ER 500 mg tablets	60505-0260-1	All lots
AvKare	1-931-292-6222	Metformin ER 500 mg tablets	42291-610-90; 42291-610-18; 42291-610-36; 42291-610-10; 50268-531-15	All lots
		Metformin ER 750 mg tablets	42291-611-18; 42291-611-50; 42291-611-90	All lots
Marksans Pharma (distributed by Time-Cap Labs)	1-631-753-9090; imcgregor@timecaplabs.com	Metformin ER 500 mg tablets	49483-623-01	XP9004 (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 here. Commonly asked questions about NDMA impurities in metformin products can be found here.

Continued . . .

- For questions regarding these recalls, refer to the table above for manufacturer contact information.

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