Metformin ER 500 mg Tablets

Date: 06/05/2020

At Magellan Rx Management, we want to help you get the best possible care. We have created a site to share drug recall information.

Marksans Pharma Limited has posted a recall of Metformin Hydrochloride Extended-Release (ER) Tablets, 500 mg.

About this Recall:
Marksans Pharma Limited is voluntarily recalling one (1) lot of Metformin ER Tablets, 500 mg, to the consumer level.

The FDA has found the product contains N-Nitrosodimethylamine (NDMA) levels in excess of the acceptable daily intake (ADI) limit of 96 ng per day.

What this means to you:
NDMA is a substance that could cause cancer based on results from laboratory tests. NDMA is a known environmental contaminant and is found in water and foods (such as meats, dairy products, and vegetables).

The impacted metformin ER tablets can be identified by the NDC number and lot number found on the product label. The recalled NDC number, lot number, and product description are listed on the FDA Recall Notification at the link below. The FDA has stated patients should continue taking metformin tablets, even after recalls occur, until they speak with their healthcare provider who can prescribe a replacement.

Consumers with questions regarding this recall and return can contact Irene McGregor, Vice President of Regulatory Affairs for Time-Cap Labs, by phone at 1-631-753-9090, ext. 160, Monday through Friday 8 AM to 5 PM EST or by e-mail at imcgregor@timecaplabs.com.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

For more information regarding this FDA Recall Notification, please refer to the FDA website:

https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/marksans-pharma-limited-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended-release.

FDA contact information for reporting adverse events/quality complaints can be reached online at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then select prompt #2.