

Marksans Pharma Limited Issues Voluntary Nationwide Recall of Metformin ER Tablets, 500 mg, Due to the Detection of NDMA

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Marksans Pharma Limited, India is voluntarily recalling Metformin Hydrochloride Extended-Release (ER) Tablets, USP 500 mg, lot # XP9004, to the consumer level. FDA analysis has found the product contains N-Nitrosodimethylamine (NDMA) levels in excess of the Acceptable Daily Intake (ADI) limit of 96 ng/day.

Risk Statement: NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant found in water and foods, including meats, dairy products, and vegetables. Marksans Pharma has not received any reports of adverse events related to this recall to date.

Metformin Hydrochloride ER Tablets, USP 500 mg is indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus. The product is packaged in 100-count bottles with NDC 49483-0623-01. The affected Metformin ER Tablets, USP 500 mg, are white to off white, capsule shaped, biconvex tablets, debossed with '101' on one side and plain on the other side.

Product name: Metformin Hydrochloride Extended Release Tablets USP, 500 mg

Lot #: XP9004

Expiration Date (MM/YYYY): 12/2020

The product can be identified by lot # XP9004 and expiration date 12/2020. Metformin ER Tablets, USP 500 mg, lot # XP9004 was distributed by Time-Cap Labs, Inc. (located at 7 Michael Avenue, Farmingdale, New York 11735) nationwide in the United States (US) to wholesalers who further distributed to pharmacies.

Marksans Pharma Limited is notifying its distributors and customers by issuing a notification letter and press release and is arranging for return/replacement of the recalled product lot. Distributors/retailers that have

Metformin Hydrochloride ER Tablets, USP 500 mg, lot # XP9004 which is being recalled should return to the place of purchase.

Consumers with questions regarding this recall and return can contact Ms. Irene McGregor (Vice President, Regulatory Affairs) of Time-Cap Labs, Inc., located at 7 Michael Avenue, Farmingdale, New York 11735, by phone number 1-631-753-9090, ext. 160, Monday through Friday 8 AM to 5 PM EST or by e-mailing 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.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report [Online](#)
- Regular Mail or Fax: [Download form](#) or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 or call Time-Cap Labs, Inc. at 1-877-376-4271 or Fax at 631-753-2220

This recall is being conducted with the knowledge of the US Food and Drug Administration (FDA).

Company Contact Information

Consumers:

Ms. Irene McGregor (Vice President, Regulatory Affairs) of Time-Cap Labs, Inc.

631-753-9090, ext. 160

imcgregor@timecaplabs.com

Media:

Dr. Meena Rani, (US Regulatory Agent and Corporate Vice President, Regulatory Affairs & Compliance)

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Product Photos

For Product photos please refer to the FDA Link: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/marksans-pharma-limited-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended-release?utm_campaign=Marksans%20Pharma%20Limited%20Issues%20Voluntary%20Nationwide%20Recall%20of%20Metformin%20Hydrochloride&utm_medium=email&utm_source=Eloqua&elqTrackId=602E2452482D6A576158BAB61E9CFAE8&elq=3949c0d79aab41e2a18b02e9c46549c8&elqaid=12856&elqat=1&elqCampaignId=10942