

# Marksans Issues Expansion of Voluntary Nationwide Recall of Metformin HCl ER Tablets, USP 500 mg & 750 mg, Due to the Detection of NDMA

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Marksans Pharma is voluntarily expanding its earlier initiated recall on June 5, 2020 to include an additional 76 unexpired lots of Metformin Hydrochloride (HCl) Extended-Release (ER) Tablets, USP 500 mg and 750 mg to the consumer level. Marksans performed N-Nitrosodimethylamine (NDMA) testing of unexpired identified marketed lots and observed that the NDMA content in some lots was exceeding the acceptable daily intake limit (ADI) of 96 ng/day, therefore, out of an abundance of caution, an additional 76 lots are being recalled.

**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 (such as meats, dairy products, and vegetables). Marksans has not received any reports of adverse events related to this recall.

Metformin HCl ER Tablets, USP 500 mg and 750 mg are indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus. It is packaged in HDPE bottles with the following NDCs in different packing configurations:

Metformin HCl ER Tablets, USP 500 mg:

- 90 counts: 49483-0623-09
- 100 counts: 49483-0623-01
- 500 counts: 49483-0623-50
- 1,000 counts: 49483-0623-10

Metformin HCl ER Tablets, USP 750 mg:

- 100 counts: 49483-0624-01

The affected Metformin HCl 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. The impacted Metformin HCl ER Tablets, USP 750 mg, are white to off white, capsule shaped, biconvex tablets, debossed with '102' on one side and plain on the other side.

For a complete listing of recalled lot numbers and expiration dates, view the FDA recall notification: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/marksans-pharma-limited-issues-expansion-voluntary-nationwide-recall-metformin-hydrochloride>.

Metformin HCl ER Tablets, USP 500 mg and 750 mg were distributed by Time-Cap Labs nationwide in the United States (US) to wholesalers who further distributed to pharmacies. Marksans is notifying its distributors and customers by issuing a notification letter and press release and is arranging for return/replacement of recalled product lots. Distributors and customers that have affected lots of metformin HCl ER tablets that are being recalled should return to the place of purchase. The lot number can be located on the side panel of bottle labels as well as shipper/case labels.

Consumers taking these recalled product lots of metformin ER tablets are instructed by the FDA to continue taking it, until a doctor or pharmacist gives them a replacement or an alternative treatment option. It could be dangerous for patients with type 2 diabetes to stop taking their metformin without first talking to their healthcare professional (HCP). Consumers should contact their physician or HCP if they have experienced any problems that may be related to taking or using this drug product. Consumers with questions regarding this recall and return can contact Ms. Irene McGregor (Vice President, Regulatory Affairs) of Time-Cap Labs by phone number 631-753-9090, ext. 160, Monday to Friday 8 AM to 5 PM EST or by e-mail at [imcgregor@timecaplabs.com](mailto:imcgregor@timecaplabs.com).

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

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

Link to *initial* FDA recall notification: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/marksans-pharma-limited-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended-release>

Link to *expanded* FDA recall notification: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/marksans-pharma-limited-issues-expansion-voluntary-nationwide-recall-metformin-hydrochloride>

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## Company Contact Information

### Consumers:

Ms. Irene McGregor (Vice President, Regulatory Affairs) of Time-Cap Labs, Inc.  
631-753-9090; ext. 160  
[imcgregor@timecaplabs.com](mailto:imcgregor@timecaplabs.com)

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## Product Photos

Click [here](#) for product photos.