**October 6, 2020** **COM-2020-076**

# RECALL NOTIFICATION

**FDA PUBLICATION DATE:**

**October 5, 2020**

**DRUG NAME: Metformin Hydrochloride Extended-Release Tablets, USP 500mg and 750mg**

**COMPANY: Marksans Pharma Limited, Time-Cap Labs Inc.**

**REASON: Due to detection of N-Nitrosodimethylamine (NDMA) Impurity**

**Dear provider of pharmaceutical services,**

PharmPix is committed to the health and wellness of our members. The clinical team wants to communicate you with the latest up-to-date information on drug safety. For this reason, we are notifying that on October 5, 2020, the US Food and Drug Administration (FDA) published a voluntary recall for an additional 76 lots of Metformin Hydrochloride Extended-Release tablets manufactured by Marksans Pharma Limited, and distributed by Time-Cap Labs Inc.

The voluntary recall is due to the detection of N-Nitrosodimethylamine (NDMA) impurity above the allowable Acceptable Daily Intake (ADI) limit of 96 ng/day. NDMA is a compound classified as a probable carcinogen to the human population. Patients taking the recalled products should continue taking it and contact their physician for advice regarding an alternative treatment.

See the complete list of the newly recalled products here. (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/marksans-pharma-limited-issues-expansion-voluntary-nationwide-recall-metformin-hydrochloride )

**Pharmacy required actions(s):**

- Identify if the product is inventory and immediately stop using and dispensing it. The product should be a return to the place of purchase or as directed in the recall notification.



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- Advise patients that they should not discontinue the medication without contacting their healthcare provider for guidance or a replacement prescription.
- For further information: Contact Ms. Irene McGregor (Vice President, Regulatory Affairs) of Time-Caps Labs, Inc. by phone number 631-753-9090; ext. 160 or email imcgregor@timecaplabs.com for the questions about the recalled product and the return process. Marksans Pharma Limited will notify distributors and customers for the arrangement of the returns.

**Contact information**:

Remember, you can report adverse events or side effects at MedWatch: The FDA Safety Information and Adverse Event Reporting Program by any of the following ways:

- Complete and submit the MedWatch Online Voluntary Reporting Form online.
- Download FDA Form 3500 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.

Additional information can be found at:

- FDA Recall for Metformin Marksans Pharma Limited
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program

If you have any questions or wish to have more information regarding this document, you can call us at 787-522-5252, extension 137. In addition, know that you can access our recent communications at our providers' portal: https://www.pharmpix.com/providers/.

Regards,

PharmPix Clinical Department

Reference(s):

U.S. Food and Drug Administration. (2020). Marksans Pharma Limited Issues Expansion of Voluntary Nationwide Recall of Metformin Hydrochloride Extended-release tablets, USP 500mg and 750mg Due to Detection of N-Nitrosodimethylamine (NDMA). Retrieved on October 6, 2020 from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/marksans-pharma-limited-issues-expansion-voluntary-nationwide-recall-metformin-hydrochloride.