RXADVANCE
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# Metformin Hydrochloride ER Tablets Recall Alert

Date of Notice: 06/02/2020

## Brief Description of Recall Alert

Marksans Pharma Limited, India is voluntarily recalling metformin hydrochloride extended-release (ER) tablets, USP 500mg. The FDA has found the drug to contain N-Nitrosodimethylamine (NDMA) levels in above acceptable amounts.

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.

## Affected Products

| Drug Name & Strength | NDC | Lot | Expiration Date |
|---|---|---|---|
| metformin HCl ER tablets USP, 500 mg | 49483-623-01 | XP9004 | 12/2020 |

## Prescriber Information

Adverse reactions or quality problems experienced with the use of this drug 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

## Member Information

Members 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 631-753-9090; ext. 160, [Monday to Friday 8am-5pm EST] or e-mail address imcgregor@timecaplabs.com.

Members should contact their doctor if they have experienced any problems that may be related to taking or using this drug.

## RxAdvance Response

Members should continue taking metformin until a doctor or pharmacist provides replacement drug (if needed) or a different treatment option.