

## COMPANY ANNOUNCEMENT

# Marksans Pharma Limited Issues Expansion of Voluntary Nationwide Recall of Metformin Hydrochloride Extended-Release Tablets, USP 500mg & 750mg, Due to the Detection of N-Nitrosodimethylamine (NDMA)

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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## Summary

**Company Announcement Date:**

October 02, 2020

**FDA Publish Date:**

October 05, 2020

**Product Type:**

Drugs

**Reason for Announcement:**

Due to the Detection of N-Nitrosodimethylamine (NDMA) Impurity

**Company Name:**

Marksans Pharma Limited

**Brand Name:**

Time-Cap Labs Inc.

**Product Description:**

Metformin Hydrochloride for Extended-Release Tablets, USP 500 mg and 700 mg

## Company Announcement

Marksans Pharma Limited, India is voluntarily expanding its earlier initiated recall on June 05, 2020 to include an additional 76 unexpired lots of Metformin Hydrochloride Extended-Release Tablets, USP 500mg, & 750mg to the consumer level. Marksans performed N-

Nitrosodimethylamine (NDMA) testing of unexpired identified marketed lots and observed that NDMA content in some lots is exceeding the acceptable Daily Intake Limit (ADI) of 96ng/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, including meats, dairy products and vegetables. Marksans Pharma Limited has not received any reports of adverse events that have been related to this recall.

Metformin Hydrochloride Extended-Release Tablets, USP 500mg & 750mg are indicated as an adjunct to diet and exercise to improve blood glucose control in adults with type 2 diabetes mellitus and is packaged in HDPE bottles with the following NDC#s in different packing configurations-

Metformin Hydrochloride Extended-Release Tablets, USP 500mg:

90 counts: 49483-623-09

100 counts: 49483-623-01

500 counts: 49483-623-50

1000 counts: 49483-623-10

Metformin Hydrochloride Extended-Release Tablets, USP 750mg:

100 counts: 49483-624-01

The affected Metformin Hydrochloride Extended-Release Tablets, USP 500mg, are white to off white, capsule shaped, biconvex tablets, debossed with '101' on one side and plain on the other side and Metformin Hydrochloride Extended-Release Tablets, USP 750mg, are white to off white, capsule shaped, biconvex tablets, debossed with '102' on one side and plain on the other side.

S.No.	Product Name	NDC No.	Pack Size	Lot #	Expiry Date
1.	Metformin HCL ER Tablets USP 500 mg	49483-623-50	500	E037F	Oct-20
2.	Metformin HCL ER Tablets USP 500 mg	49483-623-50	90	E072F	Oct-20
3.	Metformin HCL ER Tablets USP 500 mg	49483-623-50	90	E074F	Oct-20

4.	Metformin HCL ER Tablets USP 500 mg	49483-623-10	1000	D086F	Oct-20
5.	Metformin HCL ER Tablets USP 500 mg	49483-623-50	500	G011F	Oct-20
6.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	E076F	Oct-20
7.	Metformin HCL ER Tablets USP 500 mg	49483-623-01	100	XP8260	Oct-20
8.	Metformin HCL ER Tablets USP 500 mg	49483-623-10	1000	G012F	Nov-20
9.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	D096F	Nov-20
10.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	XP8276	Nov-20
11.	Metformin HCL ER Tablets USP 500 mg	49483-623-50	500	F001F	Nov-20
12.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	H029F	Nov-20
13.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	H031F	Nov-20

<b>S.No.</b>	<b>Product Name</b>	<b>NDC No.</b>	<b>Pack Size</b>	<b>Lot #</b>	<b>Expiry Date</b>
14.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	XP8289	Nov-20
15.	Metformin HCL ER Tablets USP 500 mg	49483-623-50	500	H041F	Dec-20
16.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	L007F	Dec-20
17.	Metformin HCL ER Tablets USP 500 mg	49483-623-10	1000	L008F	Dec-20
18.	Metformin HCL ER Tablets USP 500 mg	49483-623-50	500	L009F	Dec-20
19.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	J022F	Dec-20

20.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	H039F	Dec-20
21.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	J092F	Jan-21
22.	Metformin HCL ER Tablets USP 500 mg	49483-623-10	1000	K042F	Feb-21
23.	Metformin HCL ER Tablets USP 500 mg	49483-623-50	500	K051F	Jun-21
24.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	L055F	Jun-21
25.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	K079F	Jul-21
26.	Metformin HCL ER Tablets USP 500 mg	49483-623-10	1000	M001F	Jul-21
27.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	A002G	Aug-21
28.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	A003G	Aug-21

<b>S.No.</b>	<b>Product Name</b>	<b>NDC No.</b>	<b>Pack Size</b>	<b>Lot #</b>	<b>Expiry Date</b>
29.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	A007G	Aug-21
30.	Metformin HCL ER Tablets USP 500 mg	49483-623-50	500	A115G	Sep-21
31.	Metformin HCL ER Tablets USP 500 mg	49483-623-50	500	A010G	Sep-21
32.	Metformin HCL ER Tablets USP 500 mg	49483-623-10	1000	A009G	Sep-21
33.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	A49001	Nov-21
34.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	A40001	Dec-21
35.	Metformin HCL ER Tablets USP 500 mg	49483-623-10	1000	A40002	Dec-21

36.	Metformin HCL ER Tablets USP 500 mg	49483-623-01	100	XP0010	Dec-21
37.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	A40003	Dec-21
38.	Metformin HCL ER Tablets USP 500 mg	49483-623-10	1000	A40004	Dec-21
39.	Metformin HCL ER Tablets USP 500 mg	49483-623-01	100	XP0016	Dec-21
40.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	A40005	Dec-21
41.	Metformin HCL ER Tablets USP 500 mg	49483-623-50	500	A40006	Jan-22
42.	Metformin HCL ER Tablets USP 500 mg	49483-623-50	500	A40007	Jan-22
43.	Metformin HCL ER Tablets USP 500 mg	49483-623-50	500	A40008	Jan-22

<b>S.No.</b>	<b>Product Name</b>	<b>NDC No.</b>	<b>Pack Size</b>	<b>Lot #</b>	<b>Expiry Date</b>
44.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	A40009	Feb-22
45.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	A40010	Mar-22
46.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	XP0036	Mar-22
47.	Metformin HCL ER Tablets USP 500 mg	49483-623-50	500	A40011	Mar-22
48.	Metformin HCL ER Tablets USP 500 mg	49483-623-10	1000	A40012	Mar-22
49.	Metformin HCL ER Tablets USP 500 mg	49483-623-01	100	XP0046	Apr-22
50.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	A40013	Mar-22
51.	Metformin HCL ER Tablets USP 500 mg	49483-623-10	1000	A40014	Apr-22

52.	Metformin HCL ER Tablets USP 500 mg	49483-623-09	90	A40015	Apr-22
53.	Metformin HCL ER Tablets USP 500 mg	49483-623-50	500	A40016	Apr-22
54.	Metformin HCL ER Tablets USP 500 mg	49483-623-10	1000	A40017	Apr-22
55.	Metformin HCL ER Tablets USP 500 mg	49483-623-50	500	A40018	Apr-22
56.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	M125E	Oct-20
57.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	D001F	Nov-20
58.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	C084F	Nov-20

<b>S.No.</b>	<b>Product Name</b>	<b>NDC No.</b>	<b>Pack Size</b>	<b>Lot #</b>	<b>Expiry Date</b>
59.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	F073F	Jan-21
60.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	E063F	Jan-21
61.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	F072F	Mar-21
62.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	J002F	Apr-21
63.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	J087F	Apr-21
64.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	K080F	Jun-21
65.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	L056F	Jun-21
66.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	M046F	Jul-21
67.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	9R9001	Oct-21

68.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	9R9002	Nov-21
69.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	9R0001	Dec-21
70.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	9R0002	Dec-21
71.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	9R0003	Mar-22
72.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	XR0016	Mar-22
73.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	9R0004	Mar-22

S.No.	Product Name	NDC No.	Pack Size	Lot #	Expiry Date
74.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	9R0005	Mar-22
75.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	9R0006	Apr-22
76.	Metformin HCL ER Tablets USP 750 mg	49483-624-01	100	9R0007	Apr-22

Metformin Hydrochloride Extended-Release Tablets, USP 500mg & 750 mg were distributed by Time-Cap Labs, Inc. (located at 7 Michael Avenue, Farmingdale, New York 11735) nationwide in the USA to wholesalers who further distributed to pharmacies.

Marksans Pharma Limited is notifying its distributors and customers by issuing notification letter and press release and is arranging for return/replacement etc. of recalled product lots. Distributors //customers that have affected lots of Metformin Hydrochloride Extended- Release Tablets, USP 500mg & 750mg those are being recalled should return to place of purchase. The lot # can be located on the side panel of bottle labels as well as shipper/case labels.

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 631-753-9090; ext. 160, [Monday to Friday 8am-5pm EST] or e-mail address [imcgregor@timecaplabs.com](mailto:imcgregor@timecaplabs.com) (<mailto:imcgregor@timecaplabs.com>).

Consumers taking these recalled product lots of Metformin ER Tablets should continue taking it until a doctor or pharmacist gives them a replacement or a different treatment option. It could be dangerous for patients with type 2 diabetes to stop taking their metformin without first talking to their health care professional. Consumer 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 (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>)
- Regular Mail or Fax: Download form (</safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>) 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 U.S. Food and Drug Administration.

Initial press release (<http://wcms-internet.fda.gov/safety/recalls-market-withdrawals-safety-alerts/marksans-pharma-limited-issues-voluntary-nationwide-recall-metformin-hydrochloride-extended-release>)

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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) (<mailto:imcgregor@timecaplabs.com>)

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## Product Photos



NDC 49483-**623**-09



**METFORMIN  
HYDROCHLORIDE  
EXTENDED-RELEASE  
TABLETS, USP**

**500 mg**

PHARMACIST: Dispense the Patient Information  
Leaflet provided separately to each patient.

Rx only      90 Tablets

Each tablet contains:  
Metformin Hydrochloride, USP 500 mg

**DOSAGE AND USE**  
See package insert for complete product information.

Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° – 30°C (59° – 86°F) [See USP Controlled Room Temperature]. Dispense in a light-resistant container as defined in the USP.

Manufactured for: **Time-Cap Labs, Inc.**  
7 Michael Avenue  
Farmingdale, NY 11735, USA

Manufactured by: **Marksans Pharma Ltd.**  
Plot No. L-82, L-83, Verna Indl. Estate,  
Verna, Goa-403 722, India  
623R 0717

Code No.: GO/DRUGS/515



XPIL312

3 49483-623-09 3

NDC 49483-**623**-01



**METFORMIN  
HYDROCHLORIDE  
EXTENDED-RELEASE  
TABLETS, USP**

**500 mg**

PHARMACIST: Dispense the Patient Information  
Leaflet provided separately to each patient.

Rx only      100 Tablets

Each tablet contains:  
Metformin Hydrochloride, USP 500 mg

**DOSAGE AND USE**  
See package insert for complete product information.

Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° – 30°C (59° – 86°F) [See USP Controlled Room Temperature]. Dispense in a light-resistant container as defined in the USP.

Manufactured for: **Time-Cap Labs, Inc.**  
7 Michael Avenue  
Farmingdale, NY 11735, USA

Manufactured by: **Marksans Pharma Ltd.**  
Plot No. L-82, L-83, Verna Indl. Estate,  
Verna, Goa-403 722, India  
623R 0717

Code No.: GO/DRUGS/515



XPIL313

3 49483-623-01 7

NDC 49483-**623**-50



**METFORMIN  
HYDROCHLORIDE  
EXTENDED-RELEASE  
TABLETS, USP**

**500 mg**

PHARMACIST: Dispense the Patient Information  
Leaflet provided separately to each patient.

Rx only      500 Tablets

Each tablet contains:  
Metformin Hydrochloride, USP 500 mg

**DOSAGE AND USE**  
See package insert for complete product information.

Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° – 30°C (59° – 86°F) [See USP Controlled Room Temperature].

Dispense in a light-resistant container as defined in the USP.

Manufactured for:  
**Time-Cap Labs, Inc.**  
7 Michael Avenue  
Farmingdale, NY 11735, USA

Manufactured by:  
**Marksans Pharma Ltd.**  
Plot No. L-82, L-83, Verna Indl. Estate,  
Verna, Goa-403 722, India      623R 0717

Code No.: GO/DRUGS/515



XPIL314

3 49483-623-50 5

NDC 49483-**623**-10



**METFORMIN  
HYDROCHLORIDE  
EXTENDED-RELEASE  
TABLETS, USP**

**500 mg**

PHARMACIST: Dispense the Patient Information  
Leaflet provided separately to each patient.

Rx only      1000 Tablets

Each tablet contains:  
Metformin Hydrochloride, USP 500 mg

**DOSAGE AND USE**  
See package insert for complete product information.


Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° – 30°C (59° – 86°F) [See USP Controlled Room Temperature].

Dispense in a light-resistant container as defined in the USP.

Manufactured for:  
**Time Cap Labs, Inc.**  
7 Michael Avenue  
Farmingdale, NY 11735, USA

Manufactured by:  
**Marksans Pharma Ltd.**  
Plot No. L-82, L-83, Verna Indl. Estate,  
Verna, Goa-403 722, India  
623R 0717

Code No.: GO/DRUGS/515



XPIL315

3 49483-623-10 9

NDC 49483-624-01

**Time-Cap Labs, Inc.**

**METFORMIN  
HYDROCHLORIDE  
EXTENDED-RELEASE  
TABLETS, USP**

**750 mg**

PHARMACIST: Dispense the Patient Information Leaflet provided separately to each patient.

Rx only      100 Tablets

Each tablet contains:  
Metformin Hydrochloride, USP 750 mg

**DOSAGE AND USE**  
See package insert for complete product information.

Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° – 30°C (59° – 86°F) [See USP Controlled Room Temperature]. Dispense in a light-resistant container as defined in the USP.

Manufactured for: **Time-Cap Labs, Inc.**  
7 Michael Avenue  
Farmingdale, NY 11735, USA

Manufactured by: **Marksans Pharma Ltd.**  
Plot No. L-82, L-83, Verna Indl. Estate,  
Verna, Goa-403 722, India  
624R 0717

XRL1316 Code No: GO/DRUGS/515  
3 49483-624-014

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