RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Metformin Hydrochloride ER Tablets Recall Alert

Date of Notice: 10/05/2020

Brief Description of Recall Alert

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. 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; therefore, out of an abundance of caution, an additional 76 lots are being recalled.

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	49483-623-50	E037F E072F E074F G011F	10/2020
metformin HCl ER tablets, USP 500 mg	49483-623-10	D086F	10/2020
metformin HCl ER tablets, USP 500 mg	49483-623-09	E076F	10/2020
metformin HCl ER tablets, USP 500 mg	49483-623-01	XP8260	10/2020
metformin HCl ER tablets, USP 500 mg	49483-623-10	G012F	11/2020
metformin HCl ER tablets, USP 500 mg	49483-623-09	D096F H029F H031F XP8276 XP8289	11/2020
metformin HCl ER tablets, USP 500 mg	49483-623-50	F001F	11/2020
metformin HCl ER tablets, USP 500 mg	49483-623-50	H041F L009F	12/2020
metformin HCl ER tablets, USP 500 mg	49483-623-09	H039F J022F L007F	12/2020
metformin HCl ER tablets, USP 500 mg	49483-623-10	L008F	12/2020
metformin HCl ER tablets, USP 500 mg	49483-623-09	J092F	01/2021

metformin HCl ER tablets, USP 500 mg	49483-623-10	K042F	02/2021
metformin HCl ER tablets, USP 500 mg	49483-623-50	K051F	06/2021
metformin HCl ER tablets, USP 500 mg	49483-623-09	L055F	06/2021
metformin HCl ER tablets, USP 500 mg	49483-623-09	K079F	07/2021
metformin HCl ER tablets, USP 500 mg	49483-623-10	M001F	07/2021
metformin HCl ER tablets, USP 500 mg	49483-623-09	A002G A003G A007G	08/2021
metformin HCl ER tablets, USP 500 mg	49483-623-50	A010G A115G	09/2021
metformin HCl ER tablets, USP 500 mg	49483-623-10	A009G	09/2021
metformin HCl ER tablets, USP 500 mg	49483-623-09	A49001	11/2021
metformin HCl ER tablets, USP 500 mg	49483-623-09	A40001 A40003 A40005	12/2021
metformin HCl ER tablets, USP 500 mg	49483-623-10	A40002 A40004	12/2021
metformin HCl ER tablets, USP 500 mg	49483-623-01	XP0010 XP0016	12/2021
metformin HCl ER tablets, USP 500 mg	49483-623-50	A40006 A40007 A40008	01/2022
metformin HCl ER tablets, USP 500 mg	49483-623-09	A40009	02/2022
metformin HCl ER tablets, USP 500 mg	49483-623-09	A40010 A40013 XP0036	03/2022
metformin HCl ER tablets, USP 500 mg	49483-623-50	A40011	03/2022
metformin HCl ER tablets, USP 500 mg	49483-623-10	A40012 A40014	03/2022
metformin HCl ER tablets, USP 500 mg	49483-623-01	XP0046	04/2022
metformin HCl ER tablets, USP 500 mg	49483-623-09	A40015	04/2022
metformin HCl ER tablets, USP 500 mg	49483-623-50	A40016 A40018	04/2022
metformin HCl ER tablets, USP 500 mg	49483-623-10	A40017	04/2022
metformin HCl ER tablets, USP 750 mg	49483-624-01	M125E	10/2020
metformin HCl ER tablets, USP 750 mg	49483-624-01	C084F D001F	11/2020

metformin HCl ER tablets, USP 750 mg	49483-624-01	E063F F073F	01/2021
metformin HCl ER tablets, USP 750 mg	49483-624-01	F072F	03/2021
metformin HCl ER tablets, USP 750 mg	49483-624-01	J002F J087F	04/2021
metformin HCl ER tablets, USP 750 mg	49483-624-01	K080F L056F	06/2021
metformin HCl ER tablets, USP 750 mg	49483-624-01	M046F	07/2021
metformin HCl ER tablets, USP 750 mg	49483-624-01	9R9001	10/2021
metformin HCl ER tablets, USP 750 mg	49483-624-01	9R9002	11/2021
metformin HCl ER tablets, USP 750 mg	49483-624-01	9R0001 9R0002	12/2021
metformin HCl ER tablets, USP 750 mg	49483-624-01	9R0003 9R0004 9R0005 XR0016	03/2022
metformin HCl ER tablets, USP 750 mg	49483-624-01	9R0006 9R0007	04/2022

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.