September 24, 2020 **COM-2020-070**

RECALL NOTIFICATION

FDA PUBLICATION DATE:

September 23, 2020

DRUG NAME: RIOMET ER™

COMPANY: Sun Pharmaceutical Industries, 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. It is for this reason, that we are notifying you that on September 23, 2020, the US Food and Drug Administration (FDA) published a voluntary recall for one lot of RIOMET ER™ (metformin hydrochloride for extended-release oral suspension) manufactured by Sun Pharmaceutical Industries (also known as SUN PHARMA).

Product	NDC	Lot Number	Exp. date
RIOMET ER™ (500mg/ 5 mL)	10631-019-17	AB06381	10/2021

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

Pharmacy required actions(s):

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

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- Advise patients that they should not discontinue using the medication without contacting their healthcare provider for guidance or a replacement prescription.
- For further information: Contact SUN PHARMA by calling 1-800-818-4555 or e-mailing drug.safetyUSA@sunpharma.com for the questions about the recalled product. SUN PHARMA will notify distributors and customers through Inmar, Inc. (a recall coordinator) to arrange 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 the 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 RIOMET ER
- 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). Sun Pharmaceutical Industries, Inc. Issues Voluntary Nationwide Recall of RIOMET ER™ (Metformin hydrochloride for Extended-Release oral suspension) due to N-Nitrosodimethylamine (NDMA) content above the Acceptable Daily Intake (ADI) limit. Retrieved September 24, 2020 from https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sun-pharmaceutical-industries-inc-issues-voluntary-nationwide-recall-riomet-ertm-metformin#:~:text=(SUN%20PHARMA)%2C%20a%20wholly,mL%20to%20the%20consumer%20level.&text=To%20date%2C%20SUN%20PHARMA%20has,events%20related%20to%20this%20recall.

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