RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Riomet ER™ Recall Alert

Date of Notice: 09/23/2020

Brief Description of Recall Alert

Sun Pharmaceutical Industries, Inc. (Sun Pharma), a wholly owned subsidiary of Sun Pharmaceutical Industries Ltd. is voluntarily recalling one lot of Riomet ER™ (metformin hydrochloride for extended-release oral suspension), 500 mg per 5 mL to the consumer level. The reason for the recall is due to the level of N-Nitrosodimethylamine (NDMA), which has been found to be above the allowable acceptable daily intake (ADI) limit established by the U.S. Food and Drug Administration (FDA).

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
Riomet ER™ (metformin hydrochloride for extended-release oral suspension), 500 mg per 5 mL	10631-019-17	AB06381	05/2021

Prescriber Information

To date, Sun Pharma has not received any reports of adverse events related to this recall.

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

Sun Pharma is notifying its distributors and customers through its third-party Recall Coordinator (Inmar Inc.), via FedEx standard overnight shipping and will arrange for return of all recalled products.

Distributors and retailers that have Riomet ER™ (metformin hydrochloride for extended release oral suspension), which is being recalled, should stop distributing and return it to place of purchase or as directed in the recall notification.

Patients taking Riomet ER™ (metformin hydrochloride for extended-release oral suspension), 500 mg per 5 mL are advised to continue taking their medication and contact their pharmacist, physician, or medical provider for advice regarding an alternative treatment. According to the U.S. Food & Drug Administration, it could be dangerous for patients with this serious condition to stop taking their metformin without first talking to their health care professionals. Please visit the agency's website for more information at https://www.fda.gov/drugs/drug-safety-andavailability/fda-updates-and-press-announcements-ndma-metformin.

Consumers with questions regarding this recall can contact Sun Pharma by calling 1-800-818-4555 Monday through Friday between 8:00 am and 5:00 pm EST or by e-mailing drug.safetyUSA@sunpharma.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

RxAdvance Response

RxAdvance is in the process of contacting members and prescribers to advise them of this recall. Members should continue taking metformin until a doctor or pharmacist provides replacement drug (if needed) or a different treatment option.