COMPANY ANNOUNCEMENT

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

Summary

Company Announcement Date:

September 23, 2020

FDA Publish Date:

September 23, 2020

Product Type:

Drugs

Reason for Announcement:

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

Company Name:

Sun Pharmaceutical Industries

Brand Name:

Riomet ER

Product Description:

Metformin Hydrochloride for Extended-Release Oral Suspension

Company Announcement

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.

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 and found in water and foods, including meats, dairy products, and vegetables. To date, SUN PHARMA has not received any reports of adverse events related to this recall.

RIOMET ER™ (metformin hydrochloride for extended-release oral suspension) is a prescription oral medication indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus. RIOMET ER™, when reconstituted, is packaged in a 16 oz. (473 mL) round bottle. Each carton contains one bottle of drug pellets, one bottle of diluent, and one dosing cup. The affected RIOMET ER™ is the following lot:

Product Name	Lot Number	NDC Number	Expiration Date	Number of Units
RIOMET ER™ (metformin hydrochloride for extended-release oral suspension), 500 mg per 5 mL	AB06381	10631-019-17	10/2021	747 cartons

The product can be identified by the bottles or carton labeled as RIOMET ER™ (metformin hydrochloride for extended-release oral suspension), containing the specific Lot Number and Expiration Date referenced above or on the labeling below. The product was distributed nationwide to wholesale customers.

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-and (https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin)availability/fda-updates-and-press-announcements-ndma-metformin (https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin). (https://www.fda.gov/drugs/drug-safety-and-availability/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 to 5:00 pm EST or e-mailing drug.safetyUSA@sunpharma.com (mailto: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.

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.

Company Contact Information

Consumers:

SUN PHARMA

1-800-818-4555

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Product Photos

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