Sun Pharma Issues Voluntary Nationwide Recall of Riomet ER™ (metformin HCl for ER oral suspension) due to NDMA

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Sun Pharma is voluntarily recalling 1 lot of Riomet ER™ (metformin hydrochloride [HCl] for extended-release [ER] 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 acceptable daily intake (ADI) limit established by the United States (US) 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 and is found in water and foods, such as meats, dairy products, and vegetables. To date, Sun Pharma has *not* received any reports of adverse events related to this recall.

Riomet ER (metformin HCl for ER 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 1 bottle of drug pellets, 1 bottle of diluent, and 1 dosing cup. The affected Riomet ER is the following lot:

Product Name	Lot Number	NDC Number	Expiration Date	Number of Units
Riomet ER (metformin HCl for ER 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 HCl for ER oral suspension), containing the specific lot number and expiration date referenced above or on the product photos linked below. The product was distributed nationwide to wholesale customers.

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

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

Patients taking Riomet ER (metformin HCl for ER 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 US FDA, it could be dangerous for patients with this serious condition to stop taking their metformin without first talking to their healthcare professionals (HCPs). 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 to 5:00 pm EST or e-mailing drug.safetyUSA@sunpharma.com. Consumers should contact their physician or HCP 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
- 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.

This recall is being conducted with the knowledge of the US FDA.

Link to FDA recall notification: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sun-pharmaceutical-industries-inc-issues-voluntary-nationwide-recall-riomet-ertm-metformin

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Company Contact Information

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Product Photos

Click here for product photos.