

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

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At Magellan Rx Management, we want to help you get the best possible care. We have created a site to share drug recall information.

Sun Pharma has posted a lot recall of Riomet ER™ (metformin hydrochloride [HCl] for extended-release [ER] oral suspension).

About this Recall:

Sun Pharma is voluntarily recalling 1 lot of Riomet ER (metformin HCl for 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 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.

What this means to you:

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-and-availability/fda-updates-and-press-announcements-ndma-metformin>.

Riomet ER (metformin HCl for ER oral suspension) is a prescription oral medication indicated as an add-on to diet and exercise to improve blood glucose 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 product can be identified by the bottles or carton labeled as Riomet ER containing the specific NDC, lot number, and expiration date found at the FDA Recall Notification link below.

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

For more information regarding this FDA Recall Notification, please refer to the FDA website:
<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/sun-pharmaceutical-industries-inc-issues-voluntary-nationwide-recall-riomet-ertm-metformin>

FDA contact information for reporting adverse events/quality complaints can be reached online at
<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>

or by calling the FDA at 1-888-INFO-FDA (1-888-463-6332) and then select prompt #2.