



Sun Pharmaceuticals – Recall of Riomet® (metformin)

- On November 27, 2017, the [FDA announced](#) a user-level recall of two lots of [Riomet \(metformin\)](#) oral solution because these lots were found to be contaminated with *Scopulariopsis brevicaulis*.

Product Description	NDC	Lot number (expiration date)
Riomet (metformin) oral solution, 118 mL and 473 mL bottles	10631-206-01	A160031A (1/2018)
	10631-206-02	A160031B (1/2018)

- Riomet is indicated as an adjunct to diet and exercise to improve glycemic control in adults and children with type 2 diabetes mellitus.
- Use of the affected Riomet could potentially result in a risk of infection, especially in the immunocompromised patient. The most plausible portal of entry of this bacterium is the respiratory tract, where it may cause pneumonia, sinusitis and disseminated infections.
 - The bacterial contamination was discovered during sample preparation for the Antimicrobial Preservative Effectiveness Testing being performed as part of the 12 month stability study interval.
 - To date, there have been no reports of adverse events related to this recall.
- Anyone with an existing inventory of the recalled product should stop use and distribution and quarantine the product immediately.
- Patients should contact their healthcare provider if they have experienced any problems that may be related to taking or using the recalled Riomet.
- For general questions regarding this recall, contact Sun Pharmaceuticals at **1-800-406-7984**.



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at [optum.com](#).

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.