



Riomet ER™ (metformin) – New formulation approval

- On August 29, 2019, the [FDA approved](#) Sun Pharmaceuticals' [Riomet ER \(metformin\)](#) oral suspension, 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 is the first extended-release oral suspension formulation of metformin. However, various other formulations of metformin are currently available, including immediate-release and extended-release tablets and an immediate-release oral solution.
- Riomet ER carries a boxed warning for lactic acidosis.
- Riomet ER is contraindicated in patients with severe renal impairment; hypersensitivity to metformin; and acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma.
- Warnings and precautions for Riomet ER include vitamin B₁₂ deficiency and hypoglycemia with concomitant use with insulin and insulin secretagogues.
- The most common adverse reactions (> 5%) with Riomet ER use were diarrhea, nausea/vomiting, flatulence, asthenia, indigestion, abdominal discomfort, and headache.
- The recommended starting dose of Riomet ER is 500 mg (5 mL) orally once daily, with the evening meal. The dose can be increased in increments of 500 mg weekly, up to a maximum dose of 2,000 mg (20 mL) once daily.
- Sun Pharmaceuticals' launch plans for Riomet ER are pending. Riomet ER will be available as a 500 mg/5mL (reconstituted) extended-release oral suspension.



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.

©2019 Optum, Inc. All rights reserved.