

Sun Pharma launches RIOMET ER oral suspension in the US

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RIOMET ER™ (metformin hydrochloride for extended-release oral suspension) is the first and only U.S. FDA-approved extended-release liquid formulation of metformin



Sun Pharmaceutical Industries has announced that one of its wholly-owned subsidiaries has launched Riomet ER™ in the U.S. as an adjunct to diet and exercise to improve glycemic control in patients 10 years of age and older with type 2 diabetes mellitus. Riomet ER was approved by the U.S. Food and Drug Administration (FDA) on August 29, 2019.

Riomet ER, dosed once daily, is the first and only FDA-approved liquid formulation of extended-release metformin. It can be prepped and poured, thereby eliminating the need to crush the medication. The availability of a liquid formulation addresses the needs of patients with type 2 diabetes mellitus, including residents in long-term care facilities, who often have issues swallowing solid medications. Riomet ER offers dosing flexibility and an acceptable taste.

“As the fourth Sun Pharma product designed to address the needs of the 40% of U.S. adults who cannot or will not swallow solid medications, Riomet ER™ reflects our continued commitment to providing alternative formulations to underserved patient populations,” said Abhay Gandhi, CEO, North America, Sun Pharma. “Our sprinkle and liquid formulation products treat common, chronic diseases – type 2 diabetes, hypertension, elevated cholesterol, pain and depression – where adherence issues are common and can be life-threatening.”

The label for Riomet ER™ carries a boxed warning about the risk of lactic acidosis with excessive alcohol intake, as alcohol increases the effect of Riomet ER™ on lactate metabolism. The label also includes a warning about the risk of vitamin B12 deficiency, as well as a warning about the risk of hypoglycemia with concomitant use with insulin and insulin secretagogues. In placebo-controlled clinical trials of Riomet ER, the most common adverse reactions (occurring in greater than 5% of participants) were diarrhea, nausea/vomiting, flatulence, asthenia, indigestion, abdominal discomfort, and headache.

More than 30 million Americans, or about 1 person in 10 in the U.S., have diabetes. The vast majority of those individuals (90% to 95%) have type 2 diabetes¹, which is also known as non-insulin-dependent diabetes. Although type 2 diabetes can affect people of any age, the disease occurs most often in middle-aged and older people². The risk of developing type 2 diabetes is increased in people who are age 45 or older, have a family history of diabetes, or are overweight or obese.