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Sun Pharma Launches RIOMET ER Oral Suspension in the U.S.

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

New product in Sun Pharma's expanding novel portfolio designed for the 40% of American adults who cannot or will not swallow solid medication forms

Mumbai, India and Princeton, NJ, February 26, 2020 -- Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" and includes its subsidiaries and/or associate companies) today 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 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.[1] The vast majority of those individuals (90% to 95%) have type 2 diabetes[1], 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 people.[2] 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.[2]

For more information about Riomet ER™, visit RiometER.com

About Riomet ER™

Riomet ER™ is a novel liquid formulation of metformin hydrochloride extended-release, a biguanide agent used to lower blood sugar in individuals with type 2 diabetes. It is 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™ is available in 16-ounce bottles in strawberry and grape flavors, both of which were significantly preferred to crushed immediate-release metformin tablets in a taste study. The extended-release liquid formulation allows for once-daily dosing without the need to crush, break, or chew a tablet – an important consideration given that metformin pills should not be crushed, chewed, or cut. The starting dose is 500 mg (5 mL) orally once daily with the evening meal; the dose can be increased in increments of 500 mg (5 mL) weekly, up to a maximum dose of 2000 mg (20 mL) once daily with the evening meal.

Riomet ER™ is 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. It is the first and only liquid formulation of metformin hydrochloride extended-release proven to be bioequivalent to metformin extended-release tablets. In a placebo-controlled trial, long-term care residents who received extended-release metformin tablets experienced significantly fewer gastrointestinal side effects (diarrhea, nausea/vomiting) than those taking immediate-release metformin.

IMPORTANT SAFETY INFORMATION

WARNING: LACTIC ACIDOSIS

Postmarketing cases of metformin-associated lactic acidosis have resulted in death, hypothermia, hypotension, and resistant bradyarrhythmias. The onset of metformin-associated lactic acidosis is often subtle, accompanied only by nonspecific symptoms such as malaise, myalgias, respiratory distress, somnolence, and abdominal pain. Metformin-associated lactic acidosis was characterized by elevated blood lactate levels (>5 mmol/L), anion gap acidosis (without evidence of ketonuria or ketonemia), an increased lactate/pyruvate ratio; and metformin plasma levels generally >5 mcg/mL.

Risk factors for metformin-associated lactic acidosis include renal impairment, concomitant use of certain drugs (e.g., carbonic anhydrase inhibitors such as topiramate), age 65 years old or greater, having a radiological study with contrast, surgery and other procedures, hypoxic states (e.g., acute congestive heart failure), excessive alcohol intake, and hepatic impairment.

Steps to reduce the risk of and manage metformin-associated lactic acidosis in these high-risk groups are provided.

If metformin-associated lactic acidosis is suspected, immediately discontinue Riomet ER™ and institute general supportive measures in a hospital setting. Prompt hemodialysis is recommended.

CONTRAINDICATIONS

Riomet ER™ is contraindicated in patients with:

- Severe renal impairment (estimated glomerular filtration rate [eGFR] below 30 mL/min/1.73 m^2)
- Hypersensitivity to metformin
- Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma

WARNINGS AND PRECAUTIONS

- **Lactic Acidosis:** See boxed warning
- **Vitamin B12 Deficiency:** Metformin may lower vitamin B12 levels. Individuals with inadequate vitamin B12 or calcium intake or absorption appear to be predisposed to developing subnormal vitamin B12 levels. Measure hematologic parameters on an annual basis and vitamin B12 at 2 to 3 year intervals in patients on Riomet ER™ and manage any abnormalities.
- **Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues:** Insulin and insulin secretagogues (e.g., sulfonylurea) are known to cause hypoglycemia. Riomet ER™ may increase the risk of hypoglycemia when combined with insulin and/or an insulin

secretagogue. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with Riomet ER™.

ADVERSE REACTIONS

The most common adverse reactions (>5.0%) are diarrhea, nausea/vomiting, flatulence, asthenia, indigestion, abdominal discomfort, and headache.

DRUG INTERACTIONS

- **Carbonic Anhydrase Inhibitors:** may increase the risk of lactic acidosis. Consider more frequent monitoring of these patients
- **Drugs that Reduce Metformin Clearance:** (such as ranolazine, vandetanib, dolutegravir, and cimetidine) may increase the accumulation of metformin. Consider the benefits and risks of concomitant use with Riomet ER™
- **Alcohol and Medications Containing Alcohol:** Alcohol is known to increase the effect of metformin on lactate metabolism. Warn patients against excessive alcohol intake while receiving Riomet ER™
- **Drugs Affecting Glycemic Control:** Certain drugs (e.g., thiazides and other diuretics) tend to produce hyperglycemia and may lead to loss of glycemic control. When such drugs are administered concomitantly with Riomet ER™, observe the patient closely for loss of blood glucose control. When such drugs are withdrawn from a patient receiving Riomet ER™, observe the patient closely for hypoglycemia

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** Poorly controlled diabetes mellitus in pregnancy increases the maternal risk for diabetic ketoacidosis, preeclampsia, spontaneous abortions, preterm delivery, stillbirth, and delivery complications. Poorly controlled diabetes mellitus increases the fetal risk for major birth defects, stillbirth, and macrosomia-related morbidity
- **Females and Males of Reproductive Potential:** Advise premenopausal females of the potential for an unintended pregnancy. Riomet ER™ can cause ovulation, increasing the chance of getting pregnant
- **Geriatric Use:** Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range to reflect the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy, and the higher risk of lactic acidosis. Assess renal function more frequently in elderly patients
- **Hepatic Impairment:** Use of metformin in patients with hepatic impairment has been associated with some cases of lactic acidosis. Riomet ER™ is not recommended in patients with hepatic impairment

To report SUSPECTED ADVERSE REACTIONS, contact Sun Pharmaceutical Industries, Inc. at 1-800-818-4555 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see Full Prescribing Information for Riomet ER™

References:

[1] Type 2 diabetes. U.S. Department of Health & Human Services, Centers for Disease Control and Prevention; 2020. Available at: https://www.cdc.gov/diabetes/basics/type2.html. Accessed January 11, 2020.

[2] Type 2 diabetes. U.S. Department of Health & Human Services, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2020. Available at: https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes/type-2-diabetes. Accessed January 11, 2020.

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About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050)

Sun Pharma is the world's fourth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business and a skilled team enables it to deliver high-quality products, trusted by customers and patients in over 100 countries across the world, at affordable prices. Its global presence is supported by manufacturing facilities spread across 6 continents and approved by multiple regulatory agencies, coupled with a multi-cultural workforce comprising over 50 nationalities. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities across multiple R&D centers, with investments of approximately 7% of annual revenues in R&D. For further information, please visit www.sunpharma.com & follow us on Twitter @SunPharma_Live

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