

Sun Pharma launches rosuvastatin for lipid disorder treatment

16 July 2019 | News

First and only FDA-approved sprinkle formulation of rosuvastatin



Sun Pharmaceutical Industries Ltd. has announced the U.S. launch of Ezallor Sprinkle™ (rosuvastatin) capsules for the treatment of three types of elevated lipid disorders in people who have difficulty swallowing, a problem that is estimated to affect approximately 30- 35% of long-term care residents.

Ezallor Sprinkle is indicated as an adjunct to diet for the treatment of adult patients with hypertriglyceridemia, as an adjunct to diet for the treatment of adult patients with primary dysbetalipoproteinemia (type III hyperlipoproteinemia), and as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or as monotherapy if such treatments are unavailable, to reduce LDL-C, total cholesterol, and ApoB in adult patients with homozygous familial hypercholesterolemia. Ezallor Sprinkle has not been studied in Fredrickson type I and V dyslipidemias.

“With the introduction of Ezallor Sprinkle, Sun Pharma continues our commitment of providing a portfolio of alternative formulation products to address the needs of people who have difficulty swallowing, which is especially prevalent among residents in long-term care facilities,” said Abhay Gandhi, CEO, North America, Sun Pharma. “These patients often encounter more medication errors and challenges with medication administration as compared to long-term care residents who do not have difficulty swallowing.”

“The risk of medication errors increases when people have difficulty swallowing, due to crushing of medicines that shouldn’t be crushed, or from residual medication left over in crushing devices,” said Dr. Chris Chappel, certified Medical Director, Chappel Senior Care and Chappel Group Research. “This formulation will help in administering medication for patients with common types of elevated lipid disorders, especially in the geriatric population.”

Ezallor Sprinkle is formulated as extended-release-coated pellets that may be sprinkled over soft food such as applesauce, can be swallowed whole, or administered via a nasogastric tube to facilitate long-term, once-daily administration. Ezallor Sprinkle joins Kaspargo Sprinkle™ (metoprolol succinate) extended-release capsules as the second product in the Sun Pharma portfolio designed for individuals in long-term care.

Ezallor Sprinkle is contraindicated in patients with any known hypersensitivity to rosuvastatin, which may include rash, pruritus, urticaria, and angioedema; patients with active liver disease, which may include unexplained persistent elevations of hepatic transaminase levels, and females who are pregnant or breastfeeding. In the controlled clinical trials database, the most common adverse reactions with rosuvastatin were headache, myalgia, abdominal pain, asthenia, and nausea.