Select the best

CODAL-SYNTO

Rovasyn®

Rosuvastatin

Rovasyn® 5mg f.c. tablets • **Rovasyn®** 10mg f.c. tablets • **Rovasyn®** 20mg f.c. tablets • **Rovasyn®** 40mg f.c. tablets

Summary of SPC for Rovasyn®

Trade Name of the Medicinal Product:	Rovasyn®
Qualitative and Quantitative Composition:	Each film-coated tablet contains 5mg, 10mg, 20mg, 40mg of rosuvastatin as rosuvastatin calcium.
Therapeutic indications:	Treatment of hypercholesterolaemia; Prevention of Cardiovascular Events.
Posology and Method of Administration:	The recommended start dose is 5mg or 10mg orally once daily. A dose adjustment to the next dose level can be made after 4 weeks, if necessary. In light of the increased reporting rate of adverse reactions with the 40mg dose compared to lower doses, a final titration to the maximum dose of 40mg should only be considered in patients with severe hypercholesterolaemia at high cardiovascular risk, who do not achieve their treatment goal on 20mg, and in whom routine follow-up will be performed. Specialist supervision is recommended when the 40mg dose is initiated. Prevention of cardiovascular events: 20mg daily. Paediatric population: Paediatric use should only be carried out by specialists. Use in the elderly: A start dose of 5mg is recommended in patients >70 years. No other dose adjustment is necessary in relation to age. Dosage in patients with pre-disposing factors to myopathy: The recommended start dose is 5 mg. The 40mg dose is contraindicated in some of these patients.
Contra-indications:	Hypersensitivity to the active substance or to any of the excipients; Active liver disease including unexplained, persistent elevations of serum transaminases and any serum transaminase elevation exceeding 3 x the upper limit of normal (ULN); Severe renal impairment; Myopathy; Concomitant use with ciclosporin. Pregnancy and Lactation; Women of childbearing potential not using appropriate contraceptive measures. The 40mg dose is contraindicated in patients with pre-disposing factors for myopathy/rhabdomyolysis.
Special warnings and precautions for use:	Renal Effects; Skeletal Muscle Effects; Liver Effects; Race; Renal impairment, Hypothyroidism; Personal or family history of hereditary muscular disorders; Previous history of muscular toxicity with another HMG-CoA reductase inhibitor or fibrate; Alcohol abuse; Age >70 years; Concomitant use of fibrates, protease inhibitors; Lactose intolerance; Interstitial lung disease; Diabetes Mellitus; Paediatric population.
Interaction with other medicinal products and other forms of interaction:	Transporter protein inhibitors; Ciclosporin; Protease inhibitors; Gemfibrozil and other lipid-lowering products; Ezetimibe; Antacid; Erythromycin; Vitamin K antagonists; Oral contraceptive/hormone replacement therapy (HRT); Other medicinal products; Digoxin.
Undesirable Effects:	Thrombocytopenia; Hypersensitivity reactions including angioedema; Diabetes mellitus 1; Depression; Headache; Polyneuropathy; Memory loss; Sleep disturbances (including insomnia and nightmares); Cough, Dyspnoea; Constipation, Nausea Abdominal pain, Pancreatitis, Increased hepatic transaminases, Jaundice, Hepatitis, Pruritis, Rash, Urticaria, Stevens-Johnson syndrome; Myalgia, Myopathy (including myositis), Rhabdomyolysis, Arthralgia, Immune-mediated necrotising myopathy; Haematuria, Gynaecomastia, Asthenia; Proteinuria, Sexual dysfunction; Tendon disorders, sometimes complicated by rupture.
	MAH: Codal Synto Ltd.

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