ZYMPASS Abbreviated Prescribing Information. PRESENTATIONS: Zympass 10mg/10mg, 20mg/10mg and 40mg/10mg: Each film-coated tablet contains 10mg; 20mg or 40mg of rosuvastatin (as rosuvastatin calcium) respectively, and 10mg ezetimibe. **INDICATION:** Zympass is indicated for substitution therapy in adult patients who are adequately controlled with rosuvastatin and ezetimibe given concurrently at the same dose level as in the fixed combination, but as separate products, as adjunct to diet for treatment of primary hypercholesterolaemia (heterozygous familial and non-familial) or homozygous familial hypercholesterolaemia **Dosage and Administration:** The patient should be on and continue, an appropriate lipid-lowering diet, during treatment with Zympass. Zympass is not suitable for initial therapy. Treatment initiation or dose adjustment, if necessary, should only be done with the monocomponents and after setting the appropriate doses the switch to the fixed dose combination of the appropriate strength is possible. Patient should use the strength corresponding to their previous treatment. The recommended dose is one Zympass tablet daily. To be administered at any time of the day, with or without food. The tablet should be swallowed whole with a drink of water. If co-administered with bile acid sequestrant (BAS), administration of Zympass should occur either ≥2 hours before or ≥4 hours after administration of a BAS. **CONTRAINDICATIONS:** Hypersensitivity to the active substances or to any of the excipients listed in section 6.1 of SMPC; Pregnancy, breast-feeding and in women of childbearing potential not using appropriate contraceptive measures (see section 4.6). Active liver disease or unexplained persistent elevations in serum transaminases and any serum transaminase elevation exceeding 3x the upper limit of normal (ULN) (see section 4.4). In patients with severe renal impairment (creatinine clearance <30 ml/min) (see section 4.4). In patients with myopathy (see section 4.4). The 10 mg / 40 mg dose is contraindicated in patients with pre-disposing factors for myopathy/rhabdomyolysis. Such factors include: Moderate renal impairment (creatinine clearance <60 ml/min); Hypothyroidism; Personal or family history of hereditary muscular disorders; Previous history of muscular toxicity with another HMG-CoA reductase inhibitor or fibrate; Alcohol abuse; Situations where an increase in plasma levels of rosuvastatin may occur; Asian patients; Concomitant use of fibrates. **PRECAUTIONS AND WARNINGS:** Skeletal muscle effects: have been reported in rosuvastatin-treated patients with all doses and in particular with doses >20 mg. As with other HMG-CoA reductase inhibitors, reporting rate for rhabdomyolysis is associated with use at doses >40mg. Post-marketing experience with ezetimibe, cases of myopathy and rhabdomyolysis have been reported. If myopathy is suspected based on muscle symptoms or is confirmed by a creatine phosphokinase (CPK) level>10 times the ULN, Zympass and any of these other agents that the patient is taking concomitantly should be immediately discontinued. **Creatine kinase (CK) measurement:** CK should not be measured following strenuous exercise or in the presence of a plausible alternative cause of CK increase. If CK levels are significantly elevated at baseline (>5xULN) a confirmatory test should be carried out within 5-7 days. If the repeat test confirms a baseline CK >5xULN, treatment should not be started. **Liver effects:** In controlled co-administration trials in patients receiving ezetimibe with statin, consecutive transaminase elevations ≥3×ULN have been observed. It is recommended that liver function tests be carried out prior to, and 3 months following, the initiation of treatment. Rosuvastatin should be discontinued or the dose reduced if the level of serum transaminases is ≥3xULN. The reporting rate for serious events is higher at the 40mg dose. In patients with secondary hypercholesterolaemia caused by hypothyroidism or nephrotic syndrome, the underlying disease should be treated prior to initiating therapy with rosuvastatin. **Liver disease and alcohol:** As with other HMG-CoA reductase inhibitors, rosuvastatin should be used with caution in patients who consume excessive quantities of alcohol and/or have a history of liver disease. **Renal effects:** Proteinuria has been observed in patients treated with higher doses of rosuvastatin and was transient or intermittent in most cases. Proteinuria has not been shown to be predictive of acute or progressive renal disease. An assessment of renal function should be considered during routine follow-up of patients treated with a dose of 40 mg. **Diabetes mellitus:** Some evidence suggests that statins raise blood glucose. This risk, however, is outweighed by the reduction in vascular risk with statins and therefore should not be a reason for stopping statin treatment. Patients at risk (fasting glucose 5.6 to 6.9 mmol/l, BMI >30 kg/m2, raised triglycerides, hypertension) should be monitored both clinically and biochemically according to national guidelines. **Pregnancy, Breast feeding and Fertility:** is contraindicated during pregnancy and breast-feeding. If a patient becomes pregnant during use of Zympass, treatment should be discontinued immediately. No clinical trial data are available on the effects of ezetimibe or rosuvastatin on human fertility. **Paediatric population:** The safety and efficacy of Zympass in children below the age of 18 years have not yet been established. **Interactions:** Contraindicated combinations: Ciclosporin. Not-recommended combinations: Fibrates and other lipid-lowering products, protease inhibitors, transporter protein inhibitors and fusidic acid. When co administering rosuvastatin with other medicinal products known to increase exposure to rosuvastatin, doses should be adjusted Full list of interactions is available in the full SmPC. The maximum daily dose should be adjusted so that the expected rosuvastatin exposure would not likely exceed that of a 40 mg daily dose of rosuvastatin taken without interacting medicinal products. **Adverse Reactions:** Adverse drug reactions previously reported with one of the individual components (ezetimibe or rosuvastatin) may be potential undesirable effects with Zympass. **Common (≥1/100 to <1/10):** diabetes mellitus, headache, dizziness, constipation, nausea, abdominal pain, diarrhoea, flatulence, myalgia, ALT and/or AST increased, asthenia and fatigue. **MARKETING AUTHORISATION HOLDER:** Sanofi-Aventis Ireland Limited T/A SANOFI, Citywest Business Campus, Dublin 24, Ireland **LEGAL CATEGORY:** Medicinal product subject to medical prescription. **Abbreviated Prescribing Information based on SmPC last revised on November 2019. Always refer to full summary of product characteristics SmPC before prescribing.**