

COMPOSITION*: Coralan 5 mg: film-coated, scored tablet containing 5 mg ivabradine; Coralan 7.5 mg film-coated tablet containing 7.5 mg ivabradine. Contains lactose as an excipient. **INDICATIONS*:** *Symptomatic treatment of chronic stable angina pectoris:* Ivabradine is indicated for the symptomatic treatment of chronic stable angina pectoris in coronary artery disease adults with normal sinus rhythm and heart rate ≥ 70 bpm. Coralan is indicated: - in adults unable to tolerate or with a contraindication to the use of beta-blockers, or – in combination with beta-blockers in patients inadequately controlled with an optimal beta-blocker dose. *Treatment of chronic heart failure:* Ivabradine is indicated in chronic heart failure NYHA II to IV class with systolic dysfunction, in adult patients in sinus rhythm and whose heart rate is ≥ 75 bpm, in combination with standard therapy including beta-blocker therapy or when beta-blocker therapy is contraindicated or not tolerated. **DOSAGE AND ADMINISTRATION*:** *Symptomatic treatment of chronic stable angina pectoris:* Ivabradine starting dose should not exceed 5 mg bid in patients <75 years (2.5 mg bid in patients ≥ 75 years). After 3 to 4 weeks of treatment, if the patient is still symptomatic, if the initial dose is well tolerated and if resting heart rate remains > 60 bpm, the dose may be increased to the next higher dose. The maintenance dose should not exceed 7.5 mg twice daily. If there is no improvement in angina symptoms within 3 months, treatment should be discontinued. *Treatment of chronic heart failure:* Ivabradine starting dose is 5 mg bid in patients <75 years (2.5 mg bid in patients ≥ 75 years). After 2 weeks of treatment, the dose can be increased to 7.5 mg bid (5 mg bid in patients ≥ 75 years) if resting heart rate is persistently > 60 bpm or decreased to 2.5 mg bid if resting heart rate is persistently < 50 bpm or in case of bradycardia. *For both indications,* if, during treatment, heart rate decreases below 50 bpm or in case of bradycardia symptoms, the dose must be titrated downward (and discontinued if it persists despite dose reduction). **CONTRAINDICATIONS*:** Hypersensitivity to the active substance or to any of the excipients; resting heart rate below 70 bpm prior to treatment; cardiogenic shock; acute myocardial infarction; severe hypotension ($< 90/50$ mmHg); severe hepatic insufficiency; sick sinus syndrome; sino-atrial block; unstable or acute heart failure; pacemaker dependent (heart rate imposed exclusively by the pacemaker); unstable angina; AV-block of 3rd degree; combination with strong cytochrome P450 3A4 inhibitors such as azole antifungals (ketoconazole, itraconazole), macrolide antibiotics (clarithromycin, erythromycin *per os*, josamycin, telithromycin), HIV protease inhibitors (nelfinavir, ritonavir) and nefazodone (see interactions section); combination with verapamil or diltiazem; pregnancy, lactation and women of child-bearing potential not using appropriate contraceptive measures (see fertility, pregnancy and breastfeeding section). **WARNINGS*:** In chronic stable angina pectoris, ivabradine is indicated only for symptomatic treatment because ivabradine has no benefits on cardiovascular outcomes in these patients. Serial heart rate measurements, ECG or ambulatory 24-hour monitoring should be considered before initiation of ivabradine treatment and when titration is considered. Cardiac arrhythmias: ivabradine is not recommended in patients with atrial fibrillation and other cardiac arrhythmias that interfere with sinus node function, monitor regularly ivabradine-treated patients for the occurrence of atrial fibrillation. In patients treated with ivabradine the risk of developing atrial fibrillation is increased. If atrial fibrillation develops during treatment, the balance of benefits and risks of continued ivabradine treatment should be carefully reconsidered. Monitor also closely patients with chronic heart failure and intraventricular conduction defects; AV-block of 2nd degree: use not recommended; low heart rate: treatment must not be initiated below 70 bpm, during treatment, if resting heart rate decreases persistently below 50 bpm or in case of symptomatic bradycardia, the dose must be down-titrated or treatment discontinued if it persists; combination with heart rate reducing calcium channel blockers (e.g. verapamil, diltiazem): contraindicated; chronic heart failure NYHA class IV patients: use with caution; stroke: not recommended immediately after a stroke; visual function: use with caution in patients with retinitis pigmentosa. Hypotension: use with caution; atrial fibrillation - cardiac arrhythmias: non urgent DC- cardioversion should be considered 24 hours after the last dose of ivabradine; patients with congenital QT syndrome or treated with QT prolonging medicinal products: use should be avoided; hypertensive patients requiring blood pressure treatment modification: blood pressure should be monitored; excipients: contains lactose. **INTERACTION(S)*:** *Contraindicated:* strong CYP3A4 inhibitors; verapamil and diltiazem. *Not recommended:* QT prolonging medicinal products, grapefruit juice. *With precautions:* Potassium-depleting diuretics (thiazide diuretics and loop diuretics), moderate CYP3A4 inhibitors, CYP3A4 inducers. **FERTILITY, PREGNANCY AND BREASTFEEDING*:** Contraindicated. Women of child-bearing potential should use appropriate contraceptive measures during treatment. **DRIVE & USE MACHINES*:** Possible occurrence of transient luminous phenomena should be taken into account. **UNDESIRABLE EFFECTS*:** *Very common:* Luminous phenomena (phosphenes). *Common:* Headache, blurred vision, dizziness, bradycardia, AV 1st degree block (ECG prolonged PQ interval), ventricular extrasystoles, atrial fibrillation, uncontrolled blood pressure. *Uncommon:* Eosinophilia, hyperuricaemia, syncope, diplopia, visual impairment, vertigo, palpitations, supraventricular extrasystoles, ECG prolonged QT interval, hypotension, dyspnoea, nausea, constipation, diarrhoea, abdominal pain, angioedema, rash, muscle spasms, asthenia, fatigue, elevated creatinine in blood. *Rare:* Erythema, pruritus, urticaria, malaise. *Very rare:* AV 2nd degree block, AV 3rd degree block, sick sinus syndrome. **OVERDOSE*.** **PROPERTIES*:** Coralan is a pure heart rate-lowering agent which acts by selective inhibition of the cardiac pacemaker I_f current which controls spontaneous depolarization in the sinus node and regulates heart rate. Coralan dose-dependently reduces heart rate. **PRESENTATION*:** Calendar pack containing 56 film-coated tablets of Coralan 5 mg; Calendar pack containing 56 film-coated tablets of Coralan 7.5 mg. **SERVIER HONG KONG LIMITED**, Flat 08-09, 43/F, Times Square Tower One, 1 Matheson Street, Causeway Bay, Hong Kong. www.servier.hk ***For complete information, please refer to the Summary of Product Characteristics for Hong Kong.**