

## IVANODE OD 10

### For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only

Abbreviated Prescribing information for IVANODE OD 10 (Ivabradine Prolonged Release Tablets 10 mg)

[Please refer the complete prescribing information for details].

### PHARMACOLOGICAL PROPERTIES:

**Mechanism of Action:** Ivabradine is a pure heart rate lowering agent, acting by selective and specific inhibition of the cardiac pacemaker  $I_f$  current that controls the spontaneous diastolic depolarisation in the sinus node and regulates heart rate. The cardiac effects are specific to the sinus node with no effect on intra-atrial, atrioventricular or intraventricular conduction times, nor on myocardial contractility or ventricular repolarisation. Ivabradine can interact also with the retinal current  $I_h$  which closely resembles cardiac  $I_f$ . It participates in the temporal resolution of the visual system, by curtailing the retinal response to bright light stimuli. Under triggering circumstances (e.g. rapid changes in luminosity), partial inhibition of  $I_h$  by ivabradine underlies the luminous phenomena that may be occasionally experienced by patients. Luminous phenomena (phosphenes) are described as a transient enhanced brightness in a limited area of the visual field.

**INDICATIONS:** It is indicated for the treatment of chronic stable angina pectoris in patients with coronary artery disease and treatment of chronic heart failure.

**DOSAGE AND ADMINISTRATION:** The Daily recommended dose is as directed by the physician Ivanode OD 10 mg tablet should be administered orally. Do not chew the tablet before swallowing.

**CONTRAINDICATION:** Hypersensitivity to the active substance or to any of the excipients, Resting heart rate below 70 beats per minute 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, Combination with verapamil or diltiazem which are moderate CYP3A4 inhibitors with heart rate reducing properties, Pregnancy, lactation and women of child-bearing potential not using appropriate contraceptive measures.

**WARNINGS & PRECAUTIONS** Lack of benefit on reported clinical outcomes in patients with symptomatic chronic stable angina pectoris Ivabradine is indicated only for symptomatic treatment of chronic stable angina pectoris because ivabradine has no benefits on cardiovascular outcomes (e.g. myocardial infarction or cardiovascular death). Precautions for use of ivabradine with Patients with hypotension , Atrial fibrillation - Cardiac arrhythmias , Use in patients with congenital QT syndrome or treated with QT prolonging medicinal products , hypertensive patients requiring blood pressure treatment modifications and the, patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

**DRUG INTERACTIONS:** The pharmacodynamics interaction caused with concomitant use of cardiovascular (e.g. quinidine, disopyramide, bepridil, sotalol) and non-cardiovascular QT prolonging medicinal products (e.g. pimozide, ziprasidone, sertindole) with ivabradine should be avoided, Concomitant use with precaution for Potassium-depleting diuretics (thiazide diuretics and loop

diuretics). The Pharmacokinetic interactions occurred with Cytochrome P450 3A4 (CYP3A4), concomitant use of potent CYP3A4 inhibitors such as azole antifungals (ketoconazole, itraconazole), macrolide antibiotics (clarithromycin, erythromycin), HIV protease inhibitors (nelfinavir, ritonavir) and nefazodone is contra-indicated, co- administration with grapefruit juice should also be avoided.

**ADVERSE REACTIONS:** Most common Rashes, Uncontrolled blood pressure while uncommon and rare are erythema, pruritus, Asthenia, possibly related to bradycardia, Angioedema, Abdominal pain, Hyperuricaemia, Eosinophilia, Elevated creatinine in blood, AV 2<sup>nd</sup> degree block, AV 3<sup>rd</sup> degree block, Sick sinus syndrome, Angioedema, Pruritus, Asthenia, possibly related to bradycardia, Elevated creatinine in blood.

**MARKETED BY:**



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(Additional information is available on request)