

IVAZINE

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

Abbreviated Prescribing information for IVAZINE [Ivabradine Tablets]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Ivabradine is a pure heart rate lowering agent, acting by selective and specific inhibition of the cardiac pacemaker If 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.

INDICATIONS: For the treatment of chronic stable angina pectoris in patients with normal sinus rhythm who have a contraindication or intolerance for Beta-blockers.

For Symptomatic Treatment of chronic stable angina pectoris in coronary artery disease patients with normal sinus rhythm, indicated in combination with beta blockers in patients inadequately controlled with an optimal beta-blocker dose and whose heart rate is >60bpm.

For treatment of chronic heart failure in chronic heart failure NYHA II to IV class with systolic dysfunction, in 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: Dosage: As directed by the Cardiologist only.

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 asazole antifungals (ketoconazole, itraconazole), macrolide antibiotics (clarithromycin, erythromycin per os, josamycin, and telithromycin), HIV protease inhibitors (nelfinavir, ritonavir) and nefazodone, Combination with verapamil or diltiazem which are moderate CYP3A4 inhibitors with heart rate reducing properties, Pregnancy and lactation and women of child-bearing potential not using appropriate contraceptive measures.

WARNINGS & PRECAUTIONS: Special warnings: Cardiac arrhythmias, Lack of benefit on clinical outcomes in patients with symptomatic chronic stable angina pectoris, Use in patients with AV-block of 2nd degree: Ivabradine is not recommended in patients with AV-block of 2nd degree, Combination with calcium channel blockers: Concomitant use of ivabradine with heart rate reducing calcium channel blockers such as verapamil or diltiazem is contraindicated, Precautions for use: Patients with hypotension Limited data are available in patients with mild to moderate hypotension, and ivabradine should therefore be used with caution in these patients, Atrial fibrillation - Cardiac arrhythmias, Use in patients with congenital QT syndrome or treated with QT prolonging medicinal products: The use of ivabradine in patients with congenital QT syndrome or treated with QT prolonging medicinal products should be avoided, Hypertensive patients requiring blood pressure treatment modifications, Excipients Since tablets contain lactose, patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

DRUG INTERACTIONS: Concomitant use not recommended: quinidine, disopyramide, bepridil, pimoziide, ziprasidone, sertindole, mefloquine, halofantrine, Potassium-depleting diuretics: (thiazide diuretics and loop diuretics, Cytochrome P450 3A4 (CYP3A4), omeprazole, lansoprazole, sildenafil, HMG CoA reductase inhibitors (simvastatin).

ADVERSE REACTIONS: The most common adverse reactions with ivabradine, luminous phenomena

(phosphenes) and bradycardia, are dose dependent and related to the pharmacological effect of the medicinal product. Nervous system disorders: Headache, generally during the first month of treatment, Dizziness, possibly related to bradycardia. Eye disorders: Blurred vision, Visual impairment, Diplopia. Cardiac disorders: Bradycardia, AV 1st degree block (ECG prolonged PQ interval), Ventricular extrasystoles, Atrial fibrillation. Vascular disorders: Uncontrolled blood pressure.

MARKETED BY:



Torrent Pharmaceuticals Limited.

IN/IVAZINE 5, 7.5 mg/Feb-2025/03/ABPI

(Additional information is available on request)