

IVANODE 5

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

Abbreviated Prescribing information for IVANODE 5 [Ivabradine Tablets 5 mg]
[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: The starting dose of ivabradine should not exceed 5mg twice daily in patients aged below 75 years in patients with symptomatic treatment of chronic stable angina pectoris. The usual recommended starting dose of ivabradine is 5 mg twice daily for treatment of chronic heart failure. Tablets must be taken orally twice daily, i.e. once in the morning and once in the evening during meals.

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 and pregnancy, lactation and women of child-bearing potential not using appropriate contraceptive measures.

WARNINGS & PRECAUTIONS: Ivabradine is indicated only for symptomatic treatment of chronic stable angina pectoris because ivabradine has no benefits on cardiovascular outcomes. Given that the heart rate may fluctuate considerably over time, serial heart rate measurements, ECG or ambulatory 24-hour monitoring should be considered when determining resting heart rate before initiation of ivabradine treatment and in patients on treatment with ivabradine when titration is considered. Ivabradine is therefore not recommended in patients with atrial fibrillation or other cardiac arrhythmias that interfere with sinus node function. Ivabradine is not recommended in patients with AV-block of 2nd degree. Ivabradine must not be initiated in patients with a pre-treatment resting heart rate below 70 beats per minute. Concomitant use of ivabradine with heart rate reducing calcium channel blockers such as verapamil or diltiazem is contraindicated. Ivabradine should be used with caution in heart failure patients with NYHA functional classification IV due to limited amount of data in this population. The use of ivabradine is not recommended immediately after a stroke since no data is available in these situations. Caution should be exercised in patients with retinitis pigmentosa. Heart rate reduction, as caused by ivabradine, may exacerbate QT prolongation, which may give rise to severe arrhythmias, in particular Torsade de pointes.

DRUG INTERACTIONS: *Concomitant use not recommended:* QT prolonging medicinal products (e.g. quinidine, disopyramide, bepridil, sotalol, ibutilide, amiodarone). *Concomitant use with precaution:* Potassium-depleting diuretics (thiazide diuretics and loop diuretics): hypokalaemia can increase the risk of arrhythmia. As ivabradine may cause bradycardia, the resulting combination of hypokalaemia and bradycardia is a predisposing factor to the onset of severe arrhythmias, especially in patients with long QT syndrome, whether congenital or substance-induced. *Contraindication of concomitant use:* The concomitant use of potent CYP3A4 inhibitors such as azole antifungals (ketoconazole, itraconazole), macrolide antibiotics (clarithromycin, erythromycin per os, josamycin, and telithromycin), HIV protease inhibitors (nelfinavir, ritonavir) and nefazodone is contraindicated.

Concomitant use not recommended: Grapefruit juice: ivabradine exposure was increased by 2-fold following the co-administration with grapefruit juice. Therefore, the intake of grapefruit juice should be avoided.

ADVERSE REACTIONS: Eosinophilia, hyperuricaemia, headache (generally during the first month of treatment), dizziness (possibly related to bradycardia), syncope (possibly related to bradycardia), luminous phenomena (phosphenes), blurred vision, diplopia, visual impairment, vertigo, bradycardia, AV 1st degree block (ECG prolonged PQ interval), ventricular extrasystoles, atrial fibrillation, palpitations, supraventricular extrasystoles, ECG prolonged QT interval, AV 2nd degree block, AV 3rd degree block, sick sinus syndrome, uncontrolled blood pressure, hypotension (possibly related to bradycardia), dyspnoea, nausea, constipation, diarrhoea, abdominal pain, angioedema, rash, erythema, pruritus, urticaria, muscle spasms, elevated creatinine in blood, asthenia (possibly related to bradycardia), fatigue (possibly related to bradycardia), malaise (possibly related to bradycardia).

MARKETED BY:

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Torrent Pharmaceuticals Limited.

IN/IVANODE 5/Feb-2026/03/ABPI

(Additional information is available on request)