

## IVANODE

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

Abbreviated Prescribing information for IVANODE (Ivabradine 5 mg & 7.5 mg Tablets) [Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)

**PHARMACOLOGICAL PROPERTIES:** - 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.

**INDICATION:** - Ivabradine film coated tablets are indicated for the symptomatic treatment of chronic stable angina pectoris in patients with normal sinus rhythm, who have a contra-indication or intolerance for beta-blockers.

**DOSAGE AND ADMINISTRATION:** The starting dose of ivabradine should not exceed 5 mg twice daily in patients aged below 75 years. After three to four weeks of treatment, if the patient is still symptomatic, if the initial dose is well tolerated and if resting heart rate remains above 60 bpm, the dose may be increased to the next higher dose in patients receiving 2.5 mg twice daily or 5 mg twice daily. The maintenance dose should not exceed 7.5 mg twice daily.

**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 3<sup>rd</sup> 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:** 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). Ivabradine is not effective in the treatment or prevention of cardiac arrhythmias, Ivabradine is not recommended in patients with AV-block of 2<sup>nd</sup> 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., The use of ivabradine is not recommended immediately after a stroke. Ivabradine influences on retinal function, Limited data are available in patients with mild to moderate hypotension, and ivabradine should therefore be used with caution in these patients.

**DRUG INTERACTIONS:** Cardiovascular QT prolonging medicinal products (e.g. quinidine, disopyramide, bepridil, sotalol, ibutilide, amiodarone), Non cardiovascular QT prolonging medicinal products (e.g. pimozide, ziprasidone, sertindole, mefloquine, halofantrine, pentamidine, cisapride, intravenous erythromycin), Potassium-depleting diuretics, Grapefruit juice, CYP3A4 inhibitors

**ADVERSE REACTIONS:** Headache, generally during the first month of treatment, dizziness, possibly related to bradycardia, luminous phenomena, blurred vision, bradycardia, AV 1<sup>st</sup> degree block (ECG prolonged PQ interval) ventricular extrasystoles, atrial fibrillation, uncontrolled blood pressure, eosinophilia, hyperuricaemia, vertigo, palpitations, supraventricular extrasystoles, uncontrolled blood pressure, dyspnoea, nausea, constipation, diarrhoea, abdominal pain, angioedema, rash, erythema pruritus, urticaria, muscle cramps, asthenia, possibly related to bradycardia, fatigue, possibly related to bradycardia, malaise, possibly related to bradycardia, elevated creatinine in blood and ECG prolonged QT interval.

**MARKETED BY:**



**TORRENT PHARMACEUTICALS LTD.**

Torrent House, Off Ashram Road,

Ahmedabad-380 009, INDIA

**IN/IVANODE 5,7.5mg /Oct-2015/01/AbPI**

(Additional information is available on request)