Ivacard

Ivabradine INN

Composition:
Ivacard-5 Tablet: Each film coated tablet contains Ivabradine Hydrochloride INN 5.39 mg equivalent to Ivabradine 5 mg.
Ivacard-7.5 Tablet: Each film coated tablet contains Ivabradine Hydrochloride INN 8.085 mg equivalent to Ivabradine 7.5 mg.

Pharmacology:
Ivabradine is the first pure heart rate lowering agent and acts by selective inhibition of cardiac pacemaker If current that controls the spontaneous diastolic depolarization in the sinus node and regulates the heart rate. This lowers the heart need for oxygen especially in the situation when an angina attack is more likely to happen and finally it reduces the number of angina attacks. 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 repolarization.

Indications:
Ivacard is a hyperpolarization-activated cyclic nucleotide-gated channel blocker indicated:
- To reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with reduced left ventricular ejection fraction
- For the treatment of stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients ages 6 months and older
- For the symptomatic treatment of chronic stable angina pectoris in coronary artery disease adults with normal sinus rhythm and heart rate ≥ 70 bpm

Dosage & administration:
Starting dose is 2.5 (pediatrics and vulnerable adults) or 5 mg twice daily with food. After 2 weeks of treatment, adjust dose based on heart rate. The maximum dose is 7.5 mg twice daily. In patients with a history of conduction defects or other patients in whom bradycardia could lead to haemodynamic compromise, initiate therapy at 2.5 mg twice daily before increasing the dose based on heart rate.

Heart Rate	Dose Adjustment
> 60 bpm	Increase dose by 2.5 mg (given twice daily) up to a maximum dose of 7.5 mg twice daily
50-60 bpm	Maintain dose as above
< 50 bpm or signs and symptoms of bradycardia	Decrease dose by 2.5 mg (given twice daily); if current dose is 2.5 mg twice daily, discontinue therapy

Contraindications:
Ivabradine is hypersensitive to any component of this preparation, Acute decompensated heart failure, significant hypotension, Sick sinus syndrome, sinoatrial block or 3rd degree AV block, significant bradycardia, severe hepatic impairment, Heart rate maintained exclusively by the pacemaker & in combination with strong cytochrome CYP3A4 inhibitors etc.

Warning and Precautions:
For fetal toxicity, women should refrain from pregnancy while taking Ivabradine; Monitor patients for atrial fibrillation; Monitor heart rate decreases and bradycardia symptoms during treatment & not recommended in patients with 2nd degree AV block.

Side effects:
Bradycardia, hypertension, atrial fibrillation, luminous phenomena, first-degree heart block, ventricular extra systoles, headache, dizziness, visual disturbances including phosphenes and blurred vision; less commonly nausea, constipation, diarrhea, palpitation, dyspnoea, vertigo, muscle cramp, eosinophilia, hyperuricemia and raised plasma-creatinine concentration.

Use in specific populations:
Use in pregnancy: Ivabradine may cause fetal harm when administered to a pregnant woman. There are no adequate and well-controlled studies of Ivabradine in pregnant women to inform any drug-associated risks; Use in lactation: Breastfeeding not recommended; Use in children & adolescents: The safety and effectiveness of Ivabradine have been established in pediatric patients (age 6 months to less than 18 years old). Safety and efficacy of Ivabradine have not been established in patients less than 6 months of age; Geriatric use: Ivabradine has only been studied in a limited number of patients ≥ 75 years of age; Hepatic Impairment: No dose adjustment is required in patients with mild or moderate hepatic impairment. Ivabradine is contraindicated in patients with severe hepatic impairment; Renal Impairment: No dosage adjustment is required for patients with creatinine clearance 15 to 60 mL/min. No data are available for patients with creatinine clearance below 15 mL/min.

Drug Interaction:
The concomitant use of potent CYP3A4 inhibitors such as azole antifungals (Ketoconazole, Itraconazole) macrolide antibiotics (Clarithromycin, Erythromycin, Telithromycin) is contraindicated, the concomitant use of Ivabradine with the heart rate reducing agent Digoxin, Amiodarone, Beta-Blockers, Diltiazem or Verapamil resulted in an increase in additional heart rate reduction.

Overdose:
Overdose may lead to severe and prolonged bradycardia. In the event of bradycardia with poor haemodynamic tolerance, temporary cardiac pacing may be required. Supportive treatment, including intravenous (IV) fluids, atropine, and intravenous beta-stimulating agents such as isoproterenol, may be considered.

Storage:
Store below 30^{0}C, Keep in a dry place and protect from light. Keep out of the reach of children.

Packing:
Ivacard-5 Tablet: Each box contains 20 tablets in blister pack
Ivacard-7.5 Tablet: Each box contains 10 tablets in blister pack.

Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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