

Ivanor™

Ivabradine

PRESENTATION

Ivanor™ 5 tablet: Each film-coated tablet contains Ivabradine Hydrochloride INN equivalent to Ivabradine 5 mg.

Ivanor™ 7.5 tablet: Each film-coated tablet contains Ivabradine Hydrochloride INN equivalent to Ivabradine 7.5 mg.

PHARMACOLOGY

Ivabradine is a pure heart rate lowering agent. It acts by selective and specific inhibition of the cardiac pacemaker I_f current that controls the spontaneous diastolic depolarization in the sinus node and regulates heart rate. By decreasing heart rate, Ivabradine decreases the cardiac workload and therefore oxygen consumption. Concomitantly, Ivabradine prolongs diastole allowing increased perfusion of coronary arteries and increased oxygen supply to the heart. 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 & USES

Symptomatic treatment of chronic stable angina pectoris in coronary artery disease patients with normal sinus rhythm. **Ivanor™** is indicated:

- In patients unable to tolerate or with a contra-indication to the use of beta-blockers, or
- In combination with beta-blockers in patients inadequately controlled with an optimal beta-blocker dose and whose heart rate is > 60 bpm.

DOSAGE AND ADMINISTRATION

The usual recommended starting dose of Ivabradine is 5 mg twice daily which may be increased after 3-4 weeks of treatment to 7.5 mg twice daily, depending on therapeutic response. Usual dose is 1 tablet in the morning and 1 tablet in the evening during meals.

If the heart rate decreases persistently below 50 bpm at rest or if symptoms related to bradycardia, the dose must be adjusted downwards to 2.5mg twice daily (one half of the 5 mg tablet twice daily). Treatment must be discontinued if heart rate remains below 50 bpm or symptoms of bradycardia persist.

Elderly: Consider a lower starting dose (2.5 mg twice daily i.e. one half 5 mg tablet twice daily).

Renal insufficiency: Use with caution in patients with creatinine clearance <15 ml/min.

Hepatic impairment: Use with caution in patients with moderate hepatic impairment; contra-indicated in severe hepatic impairment.

Children and adolescents: Not recommended.

CONTRAINDICATIONS

History of hypersensitivity to Ivabradine or any of the excipients, resting heart rate below 60 bpm before treatment, cardiogenic shock, acute myocardial infarction, severe hypotension (< 90/50 mmHg), severe hepatic insufficiency, sick sinus syndrome, sino-atrial block, heart failure, pacemaker dependent, unstable angina, 3rd degree AV

block, combination with strong cytochrome P-450 3A4 inhibitors (such as azole antifungals, macrolide antibiotics, HIV protease inhibitors).

PRECAUTION

Mild to moderate hypotension, atrial fibrillation, patients with congenital QT syndrome or treated with QT wave prolonging medicinal products, moderate hepatic insufficiency, severe renal insufficiency.

DRUG INTERACTION

QT wave prolonging medicinal products is not recommended. Cardiovascular QT wave prolonging medicinal products (e.g. Quinidine, Disopyramide, Bepridil, Sotalol, Ibutilide, Amiodarone). Non cardiovascular QT wave prolonging medicinal products (e.g. Pimozide, Ziprasidone, Sertindole, Mefloquine, Halofantrine, Pentamidine, Cisapride, Intravenous Erythromycin). The concomitant use of cardiovascular and non-cardiovascular QT wave prolonging medicinal products with Ivabradine should be avoided since QT wave prolongation may be exacerbated by heart rate reduction. If the combination appears necessary, close cardiac monitoring is needed.

SIDE EFFECT

Visual symptoms, blurred vision, bradycardia, 1st degree AV block, ventricular extrasystoles, headaches, and dizziness.

USE IN FERTILITY, PREGNANCY AND LACTATION

Fertility: Studies in rats have shown no effect on fertility in males and females.

Pregnancy: There are no or limited amount of data from the use of Ivabradine in pregnant women. Therefore, Ivabradine is contra-indicated during pregnancy.

Breast-feeding: Animal studies indicate that Ivabradine is excreted in milk. Therefore, Ivabradine is contra-indicated during breast-feeding.

STORAGE CONDITION

Store below 30° C. Protect from light and moisture. Keep out of the reach of children.

HOW SUPPLIED

Ivanor™ 5 tablet: Each box containing 20 film coated tablets in Alu-PVDC blister pack.

Ivanor™ 7.5 tablet: Each box containing 10 film coated tablets in Alu-PVDC blister pack.

Manufactured by



SQUARE

PHARMACEUTICALS LTD.
BANGLADESH