

# Ivabradine

## Coralan® 5<sub>mg</sub>

Film-coated tablet  
Anti-angina

### Description

Coralan 5 mg: Salmon-coloured, oblong, film-coated tablet scored on both sides, engraved with "5" on one face and  on the other face. The tablet can be divided into equal doses.

Coralan 7.5 mg: Salmon-coloured, triangular, film-coated tablet engraved with "7.5" on one face and  on the other face.

### Composition

The active substance is Ivabradine (as hydrochloride).

Coralan 5 mg: One film-coated tablet contains 5 mg Ivabradine (equivalent to 5.390 mg hydrochloride).

Excipient with known effect: 63.91 mg lactose monohydrate.

Coralan 7.5 mg: One film-coated tablet contains 7.5 mg Ivabradine (equivalent to 8.085 mg hydrochloride).

Excipient with known effect: 61.215 mg lactose monohydrate.

### Pharmacokinetics

Ivabradine (Coralan) is rapidly and almost completely absorbed after oral doses; absolute bioavailability is about 40% due to first-pass metabolism. Peak plasma concentrations are achieved in about 1 hour in the fasting state. Food delayed absorption by approximately 1 hour, and increased plasma exposure by 20 to 30%.

Ivabradine (Coralan) is about 70% bound to plasma proteins.

Ivabradine (Coralan) has an elimination half-life of 2 hours. Its metabolites are excreted to a similar extent in the urine and feces.

### Properties

Ivabradine (Coralan) is a heart medicine used to treat stable angina pectoris which causes chest pain, when beta-blockers (like atenolol, propranolol, metoprolol, etc. for high blood pressure, heart rhythm disorders, or angina pectoris) are not suitable.

Ivabradine (Coralan) mainly works by reducing the heart rate by a few beats per minute. This lowers the heart's need for oxygen especially in the situations when an angina attack is more likely to happen. In this way, Ivabradine (Coralan) helps to control and reduce the number of angina attacks. Furthermore, as elevated heart rate adversely affects the heart functioning and prognosis in patients with chronic heart failure, the specific heart rate lowering action of Ivabradine (Coralan) helps to reduce heart rate and hence improves the heart functioning and prognosis in these patients.

### Indications

#### Symptomatic treatment of chronic stable angina pectoris

Ivabradine (Coralan) is indicated for the symptomatic treatment of chronic stable angina pectoris in coronary artery disease adults with normal sinus rhythm and heart rate  $\geq 70$  bpm. Ivabradine (Coralan) is indicated in adults unable to tolerate or with a contraindication to the use of beta-blockers or in combination with beta-blockers in patients inadequately controlled with an optimal beta-blocker dose.

#### Treatment of chronic heart failure

Ivabradine (Coralan) is indicated in chronic heart failure NYHA II to IV class with systolic dysfunction, in adult patients in sinus rhythm and whose heart rate is  $\geq 75$  bpm, in combination with standard therapy including beta-blocker therapy or when beta-blocker therapy is contraindicated or not tolerated.

### Contraindications

Do not take Ivabradine (Coralan):

- ▶ If you are hypersensitive (allergic) to Ivabradine or to any of the other ingredients in Coralan;
- ▶ If your resting heart rate before treatment is too slow (below 70 beats per minute);
- ▶ If you are suffering from cardiogenic shock (a heart condition treated in hospital);
- ▶ If you suffer from a heart rhythm disorder;
- ▶ If you are having a heart attack;
- ▶ If you suffer from very low blood pressure;

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## Coralan® 7.5<sub>mg</sub>

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- ▶ If you suffer from unstable angina (a severe form in which chest pain occurs very frequently and with or without exertion);
- ▶ If you have heart failure which has recently become worse;
- ▶ If your heart beat is exclusively imposed by the pacemaker;
- ▶ If you suffer from severe liver problems;
- ▶ If you are already taking medicines for the treatment of fungal infections (such as ketoconazole, itraconazole), macrolide antibiotics (such as josamycin, clarithromycin, telithromycin or erythromycin given orally), medicines to treat HIV infections (such as neftinavir, ritonavir) or nefazodone (medicine to treat depression) or diltiazem, verapamil (used for high blood pressure or angina pectoris) (see "Taking other medicines");
- ▶ If you are a woman able to have children and not using reliable contraception;
- ▶ If you are pregnant or trying to become pregnant;
- ▶ If you are breastfeeding.

### Special Precautions

Take special care with Ivabradine (Coralan):

- ▶ If you suffer from heart rhythm disorders (such as irregular heartbeat, palpitation, increase in chest pain) or sustained atrial fibrillation (a type of irregular heartbeat), or an abnormality of electrocardiogram (ECG) called 'long QT syndrome';
- ▶ If you have symptoms such as tiredness, dizziness or shortness of breath (this could mean that your heart is slowing down too much),
- ▶ If you suffer from symptoms of atrial fibrillation (pulse rate at rest unusually high (over 110 beats per minute) or irregular, without any apparent reason, making it difficult to measure),
- ▶ If you have had a recent stroke (cerebral attack),
- ▶ If you suffer from mild to moderate low blood pressure,
- ▶ If you suffer from uncontrolled blood pressure, especially after a change in your antihypertensive treatment,
- ▶ If you suffer from severe heart failure or heart failure with abnormality of ECG called 'bundle branch block',
- ▶ If you suffer from chronic eye retinal disease,
- ▶ If you suffer from moderate liver problems,
- ▶ If you suffer from severe renal problems.

If any of the above applies to you, talk to your doctor before or while taking Ivabradine (Coralan).

### Use in children

Ivabradine (Coralan) is not intended for use in children and adolescents younger than 18 years.

### Taking Ivabradine (Coralan) with food and drink

Avoid grapefruit juice during treatment with Ivabradine (Coralan).

### Pregnancy

Do not take Ivabradine (Coralan) if you are pregnant or planning a pregnancy (see "Contraindications").

If you are pregnant and have taken Ivabradine (Coralan), talk to your doctor.

Do not take Ivabradine (Coralan) if you are able to become pregnant unless you use reliable contraceptive measures (see "Contraindications"). Ask your doctor or pharmacist for advice before taking any medicine.

### Breastfeeding

Do not take Ivabradine (Coralan) if you are breastfeeding. Talk to your doctor if you are breastfeeding or intending to breastfeed as breastfeeding should be discontinued if you take Ivabradine (Coralan).

Ask your doctor or pharmacist for advice before taking any medicine.

### Driving and using machines

Ivabradine (Coralan) may cause temporary luminous visual phenomena (a temporary brightness in the field of vision, see "Possible Side Effects"). If this happens to you, be careful when driving or using machines at times when there could be sudden changes in light intensity, especially when driving at night.

### Important information about some of the ingredients in Ivabradine (Coralan)

Ivabradine (Coralan) contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

#### Taking other medicines

Please inform your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even those not prescribed. Make sure to tell your doctor if you are taking any of the following medicines, as a dose adjustment of Ivabradine (Coralan) or monitoring should be required:

- ▶ Fluconazole (an antifungal agent)
- ▶ Rifampicin (an antibiotic)
- ▶ Barbiturates (for difficulty in sleeping or epilepsy)
- ▶ Phenytoin (for epilepsy)
- ▶ Hypericum perforatum or St. John's wort (herbal treatment for depression)
- ▶ QT prolonging medicines to treat either heart rhythm disorders or other conditions such as:
  - Quinidine, disopyramide, ibutilide, sotalol, amiodarone (to treat heart rhythm disorders)
  - Bepiridil (to treat angina pectoris)
  - Certain types of medicines to treat anxiety, schizophrenia or other psychoses (such as pimozide, ziprasidone, sertindole)
  - Anti-malarial medicines (such as mefloquine or halofantrine)
  - Erythromycin IV (an antibiotic)
  - Pentamidine (an antiparasitic medicine)
  - Cisapride (against the gastro-esophageal reflux)
- ▶ Some types of diuretics which may cause decrease in blood potassium level, such as furosemide, hydrochlorothiazide, indapamide (used to treat edema, high blood pressure).

#### Dosage and Administration

Always follow your doctor's instructions about how to take Ivabradine (Coralan). You should check with your doctor or pharmacist if you are not sure. Ivabradine (Coralan) should be taken during meals.

#### If you are being treated for stable angina pectoris:

The starting dose should not exceed one tablet of Ivabradine (Coralan) 5 mg twice daily. If you still have angina symptoms and if you have tolerated the 5 mg twice daily dose well, the dose may be increased. The maintenance dose should not exceed 7.5 mg twice daily. Your doctor will prescribe the right dose for you. The usual dose is one tablet in the morning and one tablet in the evening. In some cases (e.g. if you are an elderly), your doctor may prescribe half the dose i.e., one half 5 mg tablet of Coralan 5 mg (corresponding to 2.5 mg Ivabradine) in the morning and one half 5 mg tablet in the evening.

#### If you are being treated for chronic heart failure:

The usual recommended starting dose is 1 tablet of Ivabradine (Coralan) 5 mg twice daily increasing if necessary to 1 tablet of Ivabradine (Coralan) 7.5 mg twice daily. Your doctor will decide the right dose for you. The usual dose is one tablet in the morning and one tablet in the evening. In some cases (e.g. if you are an elderly), your doctor may prescribe half the dose i.e., one half tablet of Ivabradine (Coralan) 5 mg (corresponding to 2.5 mg Ivabradine) in the morning and one half 5 mg tablet in the evening.

#### **If you take more Ivabradine (Coralan) than you should**

A large dose of Ivabradine (Coralan) could make you feel breathless or tired because your heart slows down too much. If this happens, contact your doctor immediately.

#### **If you forget to take Ivabradine (Coralan)**

If you forget to take a dose of Ivabradine (Coralan), take the next dose at the usual time. Do not take a double dose to make up for the forgotten dose. The calendar printed on the blister containing the tablets should help you remember when you last took a tablet of Ivabradine (Coralan).

#### **If you stop taking Ivabradine (Coralan)**

As the treatment for angina or chronic heart failure is usually life-long, you should discuss with your doctor before stopping this medicine.

If you think that the effect of Ivabradine (Coralan) is too strong or too weak, talk to your doctor or pharmacist.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### Possible Side Effects

Like all medicines, Ivabradine (Coralan) can have side effects, although not everybody gets them.

The most common adverse reactions with this medicine are dose dependent and related to its mode of action:

Very common (may affect more than 1 in 10 people): Luminous visual phenomena (brief moments of increased brightness, most often caused by sudden changes in light intensity). They can also be described as a halo, colored flashes, image decomposition or multiple images. They generally occur within the first two months of treatment after which they may occur repeatedly and resolve during or after treatment. Common (may affect up to 1 in 10 people): Bradycardia (particularly occur within the first 2 to 3 months of treatment initiation), irregular rapid contraction of the heart, abnormal perception of heart beat, uncontrolled blood pressure, headache, dizziness, blurred vision (cloudy vision).

Uncommon (may affect up to 1 in 100 people): Palpitations and cardiac extra beats, nausea, constipation, diarrhea, abdominal pain, vertigo, dyspnea, muscle cramps, hyperuricemia, eosinophilia and elevated blood-creatinine concentrations, skin rash, angioedema (such as swollen face, tongue or throat, difficulty in breathing or swallowing), low blood pressure, fainting, fatigue, feeling of weakness, abnormal ECG heart tracing, double vision, impaired vision.

Rare (may affect up to 1 in 1000 people): Urticaria, itching, skin reddening, malaise.

Very rare (may affect up to 1 in 10000 people): Irregular heartbeats.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### Reporting of Adverse Drug Reaction

For suspected adverse drug reaction, report to the FDA at [www.fda.gov.ph](http://www.fda.gov.ph). Seek medical attention immediately at the first sign of any adverse drug reaction.

#### Overdose and Treatment

Symptoms: Overdose may lead to severe and prolonged bradycardia. Management: Severe bradycardia should be treated symptomatically in a specialized environment. In the event of bradycardia with poor hemodynamic tolerance, symptomatic treatment including intravenous beta-stimulating medicinal products such as isoprenaline may be considered. Temporary cardiac electrical pacing may be instituted if required.

#### Presentation

5 mg; 7.5 mg film-coated tablet: Aluminum/PVC blister x 14's (Box of 56's).

#### Storage Condition

This drug must be stored at temperatures not exceeding 30°C.

Keep out of the reach and sight of children.

Do not use this drug after the expiry date printed on the box.

#### Caution

Food, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

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