

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) 1986**

This medicine is to be supplied by physician's prescription only

**Coralan 5mg  
Coralan 7.5mg  
Film-coated tablets**

**Active ingredients:**

Active ingredient: **ivabradine (as hydrochloride)**.

Each Coralan 5 mg film-coated tablet contains: 5 mg ivabradine (equivalent to 5.390mg ivabradine as hydrochloride).

Each Coralan 7.5 mg film-coated tablet contains: 7.5 mg ivabradine (equivalent to 8.085mg ivabradine as hydrochloride).

Inactive ingredients and allergens: See section 6 "Additional information".

**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains essential information about this medicine. If you have any further questions, refer to the physician or the pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them even if it seems to you that their illness is similar.

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

**1. What is this medicine for?**

This medicine is used to treat:

- Stable angina pectoris, when treatment with Beta-Blockers is not suitable. The medicine should be only used in patients whose heart rate is 70 bpm or more.
- Chronic heart failure in patients whose heart rate is equal to or over 75 beats per minute. It is used in combination with standard therapy, including beta-blocker therapy or when beta-blockers are contraindicated or not suitable.

**Therapeutic group:** Cardiac therapy, other cardiac preparations.

About stable angina pectoris (usually referred to as "angina"):

Stable angina is a heart disease which happens when the heart does not receive enough oxygen. It usually appears between 40 and 50 years of age. The most common symptom of angina is chest pain or discomfort. Angina is more likely to happen when the heart beats faster in situations such as exercise, emotion, exposure to the cold or after eating. This increase in heart rate can cause the chest pain in people who suffer from angina.

About chronic heart failure:

Chronic heart failure is a disease which happens when the heart cannot pump enough blood to the rest of your body. The most common symptoms of heart failure are breathlessness, fatigue, tiredness and ankle swelling.

How does Coralan work?

Coralan mainly works by reducing the heart rate by a few beats per minute. This action lowers the heart's need for oxygen especially in the situations when an angina attack is more likely to happen. In this way Coralan helps to control and reduce the number of angina attacks.

Furthermore as elevated heart rate adversely affects the heart functioning and vital prognosis in patients with chronic heart failure, the specific heart rate lowering action of ivabradine helps to improve the heart functioning and vital prognosis in these patients.

**2. Before using this medicine**

**X Do not use this medicine if:**

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients of this medicine.
- Your resting heart rate before treatment is too slow (below 70 beats per minute).
- You are suffering from cardiogenic shock (a heart condition treated in hospital).

- You suffer from a heart rhythm disorder.
- You are having a heart attack.
- You suffer from very low blood pressure.
- You suffer from unstable angina (a severe form in which chest pain occurs very frequently and with or without exertion).
- You have heart failure which has recently become worse.
- You have a pacemaker and your heart beat is exclusively imposed by your pacemaker.
- You suffer from severe liver problems.
- 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 nelfinavir, ritonavir) or nefazodone (medicine to treat depression), or diltiazem, verapamil (used to treat high blood pressure or angina pectoris).
- You are a woman able to have children and not using reliable contraception.
- You are pregnant or trying to become pregnant.
- You are breast-feeding.

## **! Special warnings regarding the use of this medicine**

### **Before using Coralan, tell your physician if:**

- You suffer from a heart rhythm disorder (such as irregular heartbeat, palpitation, increase in chest pain) or sustained atrial fibrillation (a type of irregular heartbeat), or an abnormality arrhythmia in the electrocardiogram (ECG) called 'long QT syndrome'.
- You have symptoms such as tiredness, dizziness or shortness of breath (which may be caused by slowing the heart rate).
  - You suffer from atrial fibrillation symptoms (resting heart rate is unusually high (more than 110 bpm), or abnormal, for no apparent reason, and therefore makes it difficult to be measure).
  - You have had a recent stroke (cerebral attack).
  - You suffer from mild to moderate low blood pressure.
  - You suffer from uncontrolled blood pressure, especially after a change in your antihypertensive treatment.
  - You suffer from severe heart failure (when your heart fails to work properly) or failure with abnormality of ECG called 'bundle branch block'.
  - You suffer from chronic eye retinal disease.
  - You suffer from moderate liver problems.
  - You suffer from severe renal problems.
  - You are sensitive to any type of food or medicine.

If any of the above applies to you, talk straight away to your physician before or while taking Coralan.

**If you are taking or have recently taken other medicines, including nonprescription medications and food supplements, inform your physician or pharmacist. In particular inform your physician if you are taking any of the following medicines, as a dose adjustment of Coralan or monitoring should be required:**

- Do not use in concomitant with the following medicines:  
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 nelfinavir, ritonavir) or nefazodone (medicine to treat depression), or diltiazem, verapamil (used to treat high blood pressure or angina pectoris).

#### **Other medicines:**

- Fluconazole (an antifungal medicine),
- Rifampicin (an antibiotic),
- Barbiturates (for difficult sleeping or epilepsy),
- Phenytoin (for epilepsy),
- Hypericum perforatum or St John's Wort (herbal treatment for depression),
- ECG QT prolonging medicines to treat either heart rhythm disorders or other conditions (such as: quinidine, disopyramide, ibutilide, sotalol),
- Amiodarone (to treat heart rhythm disorders),
- Bepridil (for Angina Pectoris),
- Certain types of medicines to treat anxiety, schizophrenia or other psychosis (such as: pimozide, ziprasidone, sertindole),
- Antimalarial medicines (such as mefloquine , halofantrine),
- Intravenous erythromycin (an antibiotic),
- Pentamidine (an antiparasitic medicine),
- Cisapride (against the gastro-oesophageal reflux),

- Some types of diuretics which may cause decrease in blood potassium level, such as furosemide, hydrochlorothiazide,
- Indapamide (used to treat oedema, high blood pressure).

### **Using the medicine and food**

Swallow the medicine with water, during a meal.

Avoid consumption of grapefruit juice during treatment with this medicine.

### **Pregnancy and breast-feeding**

Do not take this medicine if you are pregnant or if you are planning to have a baby (see in "before using this medicine" above).

If you are pregnant and you have taken this medicine, inform your physician.

Do not take Coralan if you are able to become pregnant unless you use reliable contraceptive measures (see in "before using this medicine").

Do not take this medicine if you are breast-feeding (see in "before using this medicine").

Talk to your physician if you are breast-feeding or intending to breast-feed as breastfeeding should be discontinued if you take Coralan.

### **Driving and using machines**

Coralan may cause temporary luminous visual phenomena, a temporary brightness in the field of vision (see "Side effects" below). 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 medicine's ingredients**

Each 5 mg tablet contains 63.91 mg lactose Monohydrate.

Each 7.5 mg tablet contains 61.215 mg lactose Monohydrate.

If you have been told by your physician that you have an intolerance to some sugars, contact your physician before taking this medicine.

## **3. How should you use the medicine?**

Always use according to the physician's instructions. You should check with the physician or the pharmacist if you are unsure. The dosage and treatment will be determined only by the physician.

### **Treatment of stable angina pectoris:**

The starting dose will not exceed 1 tablet of Coralan 5 mg twice daily. If you still suffer from angina pectoris symptoms and the dose of 5 mg is well tolerated, the dose may be increased. The maintenance dose should not exceed 7.5 mg twice daily. Your physician 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 elderly), your physician 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 there is no improvement in symptoms of angina pectoris within 3 months after start of treatment, treatment of ivabradine should be discontinued.

If, during treatment, heart rate decreases below 50 beats per minute (bpm) at rest or you experience symptoms related to bradycardia such as dizziness, fatigue or hypotension, the dose must be decreased until the lowest dose of 2.5 mg twice daily (one half 5 mg tablet twice daily). After dose reduction, the physician will monitor the heart rate. Treatment must be discontinued if heart rate remains below 50 bpm or symptoms of bradycardia persist despite dose reduction.

### **Treatment of chronic heart failure:**

The usual recommended starting dose is:

1 tablet of Coralan 5 mg twice daily, increasing if necessary to 1 tablet of Coralan 7.5 mg twice daily.

Your physician will decide the right dose for you.

The usual dose is one tablet in the morning and one tablet in the evening, during meals.

In some cases (e.g. for elderly patient), the physician 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.

### **Do not exceed the recommended dosage.**

This medicine is to be taken at the specified time intervals as determined by the attending physician.

### **Tests and follow-up:**

**Before start using the medicine, and for purpose of dose adjustment, the physician will refer you to ECG and heart rate tests.**

Do not chew! Swallow the medicine with water.

**If you have accidentally taken a higher dose** you may feel tired or breathless, because your heart slows down too much. If this happens, contact your physician immediately.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, go immediately to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, 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 Coralan.

**If you stop taking Coralan:**

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

If you think that the effect of Coralan is too strong or too weak, talk to your physician or pharmacist.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

**4. Side effects**

As with any medicine, Coralan may cause side effects in some patients. Do not be alarmed by reading the list of side effects. You may not experience any of them.

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

Very common side effects – may affect more than one patients out of ten:

- 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, coloured 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 side effects – may affect 1-10 patients out of 100:

- Modification in the heart functioning (the symptoms are a slowing down of the heart rate). They particularly occur within the first 2 to 3 months of treatment initiation.

**Additional side effects**

Common side effects – may affect 1-10 patients out of 100:

- Abnormal perception of heartbeat,
- Uncontrolled blood pressure,
- Dizziness,
- Blurred vision (),
- Headache.

Uncommon side effects - may affect 1-10 patients out of 1,000:

- Palpitations and cardiac extra beats,
- Feeling sick (nausea), constipation, diarrhoea, abdominal pain,
- Spinning sensation (vertigo),
- Difficulty breathing (dyspnoea),
- Muscle cramps,
- Changes in laboratory parameters (blood tests): high blood levels of uric acid, an excess of eosinophils (a type of white blood cell) and elevated creatinine in blood (a breakdown product of muscle),
- Skin rash,
- Angioedema (such as swollen face, tongue or throat, difficulty in breathing or swallowing),
- Low blood pressure,
- Fainting, feeling of tiredness, feeling of weakness,
- Abnormal ECG heart tracing
- Double vision, impaired vision.

Rare side effects – may affect 1-10 patients out of 10,000:

- Urticaria (skin rash), itching, skin reddening,
- Feeling unwell.

Very rare side effects – may affect less than one patient out of 10,000:

- Irregular heartbeats.

If you experience any side effect, if any of the side effects get worse, or when you suffer side effect not mentioned in the leaflet, consult your physician immediately.

### **5. How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the blister and carton. The expiry date refers to the last day of that month.
- Even if stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of this medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.
- Store at a temperature below 30°C.

### **6. Additional information**

**In addition to the active ingredient the medicine also contains:**

Tablet core:


Lactose monohydrate, Maize starch, Maltodextrin, Magnesium stearate, Colloidal Anhydrous silica (E 551).

Tablet film-coating:


Hypromellose, Titanium dioxide (E 171), Macrogol 6000, Magnesium stearate, Glycerol, Yellow Iron oxide (E 172), Red Iron oxide (E 172).

**What does the medicine look like and what are the contents of the package:**

Coralan 5mg

Salmon coloured, oblonged, film-coated tablets, engraved with "5" on one face and \* on the other face.

Coralan 7.5mg

Salmon coloured, triangulared shaped, film-coated tablets, engraved with "7.5" on one face and \* on the other face.

Coralan is available in packs containing: 14, 28, 56, 84, 98, 100, 112 tablets.

Not all packs may be marketed.

**Registration holder:**

Mediline Ltd., City gate, Ben-Gurion 22, Herzlia.

**Manufacturer:**

Les Laboratoires Servier Industrie – France for Les Laboratoires Servier, 92284 suresnes cedex, France.

This leaflet was checked and approved by the Ministry of Health in: 03.2015

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Coralan 5mg: 142-49-32001

Coralan 7.5mg: 142-48-32002