APPROVED PIL

For

CORALAN

Registration No.:

Coralan 5 mg: A39/7.1.4/0410

Coralan 7,5 mg: A39/7.1.4/0411

Date Approved: April 2017

Confidential Information

SERVIER LABORATORIES SOUTH AFRICA (PTY) LTD
3rd Floor, Building J, Hertford Office Park, 90 Bekker Road, Vorna Valley, Midrand, 1686, Republic of South Africa - Tel. +27 (0)861 700 900 - www.servier.co.za. DIRECTORS: P. Perez *, C.M ĚP Tartar *, C.G,P Sabathier *, *French. Reg. No. 1972/014307

Coralan® 5 mg and 7,5 mg

SCHEDULING STATUS: S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

Coralan® 5 mg, film-coated tablet.

Coralan® 7,5 mg, film-coated tablet.

Read all of this leaflet carefully before you start taking Coralan®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- **Coralan®** has been prescribed to you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

Do not take Coralan® if you are pregnant and breastfeeding, as Coralan® can damage the unborn baby (see PREGNANCY AND BREASTFEEDING).

WHAT CORALAN® CONTAINS:

The active substance in **Coralan® 5 mg,** film-coated tablet is 5 mg ivabradine base.
The active substance in **Coralan® 7,5 mg,** film-coated tablet is 7,5 mg ivabradine base.
The other ingredients in the tablet core are: lactose monohydrate, magnesium stearate, maize starch, maltodextrin, colloidal anhydrous silica, and in the tablet coating: hypromellose, titanium dioxide (E171) (CI 77891), macrogol 6 000, glycerol, magnesium stearate, yellow iron oxide (E172) (CI 77492), red iron oxide (E172) (CI 77491).
Contains sugar (lactose).

WHAT CORALAN® IS USED FOR:

Coralan® is a medicine used to treat:

- Symptomatic treatment of stable chronic angina pectoris, in adult patients whose heart rate is over or equal to 70 beats per minute. It is used in adult patients who do not tolerate or cannot take heart medicines called beta-blockers, or in combination with beta-blockers in adult patients whose condition is not fully controlled with a beta-blocker.

- Chronic heart failure in adult patients whose heart rate is too high (over or equal to 77 beats per minute. It is used in combination with standard therapy, including beta-blockers therapy, or when beta-blockers are contraindicated or not tolerated.

How does Coralan® work:

Coralan® mainly works by reducing your heart rate. This lowers the heart's need for oxygen.

BEFORE TAKING CORALAN®:

Do not take Coralan®:

- If you are allergic (hypersensitive) to ivabradine or any of the ingredients of **Coralan®** listed on this leaflet;
- If you are a women able to have children and not using appropriate contraception with proven efficacy;
- if you are pregnant or trying to become pregnant;
- If you are breastfeeding;
- if your heart beat is exclusively imposed by your pacemaker;
- if your resting heart rate before treatment is too slow (below 70 beats per minute)
- if you suffer from very low blood pressure;
- if you are suffering from cardiogenic shock (a heart condition treated in hospital);
- if you have heart failure which has recently become worse, or heart failure with abnormality of ECG called bundle branch block;
- if you are having a heart attack;
- if you suffer from unstable angina (a severe form in which chest pain occurs very frequently and with or without exertion);
- Congenital (inborn) long QT syndrome on your ECG;
- if you are taking medicines for the treatment of fungal infections (such as ketoconazole, itraconazole), macrolide antibiotics (such as azithromycin,
- clarithromycin, telithromycin or erythromycin given orally), medicines to treat HIV infections (such as nelfinavir, ritonavir);
- if you are taking diltiazem, verapamil (used for high blood pressure or angina pectoris);
- if you are taking St. John's Wort;
- if you suffer from severe liver problems;
- if you suffer from a heart rhythm disorder;

- if you are taking QT-prolonging medicines to treat either heart rhythm disorders or other conditions.

Take special care with 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 or shortness of breath (this could mean 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 suffer from severe heart failure or heart failure with abnormality of ECG called bundle branch block;
- 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 chronic eye retinal disease (visual problems related to disease of the retina;
- if you suffer from liver problems;
- if you suffer from severe renal problems;
- if you have abnormal heart valves.

If any of the above applies to you, talk to your doctor before or while taking **Coralan®**.

Taking Coralan® with food and drink:

Coralan® should be taken with food.

Do not take grapefruit juice during treatment with **Coralan®**.

PREGNANCY AND BREASTFEEDING:

Do not take Coralan® if you are pregnant and/or breastfeeding, as Coralan® has shown to be cause deformities in animal reproductive studies.

You should not take **Coralan®** if you are pregnant or breastfeeding.
Should you become ~~a~~ pregnant while using **Coralan®** you must immediately stop~~ped~~ taking it, and consult your doctor without delay.
Do not take **Coralan®** if you are able to become pregnant, unless you use appropriate contraception with proven efficacy.
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice, before taking Coralan®.

Driving and using machinery:
Coralan® may cause temporary visual disturbances and dizziness. If this happens to you be careful when driving vehicles or operating machines, particularly at times when there could be sudden changes in light intensity.

Important information about some of the ingredients of Coralan®:
Coralan® contains lactose.
Patients with hereditary conditions of lactose/fructose or galactose intolerance should not take **Coralan®**.
If you have been told by your doctor that you have intolerance to lactose (milk sugar), contact your doctor before taking **Coralan®**.

Taking other medicines with Coralan®:
Always tell your healthcare professional if you are taking any other medicines (This includes complimentary of traditional medicines).
Make sure to tell your doctor if you are taking any of the following medicines, as a dose adjustment of **Coralan®** or monitoring may be required:
- fluconazole (an antifungal medicine);
- rifampicin (an antibiotic, used for TB);
- barbiturates (for difficultly in sleeping or epilepsy);
- phenytoin (for epilepsy);
- St John's Wort (*Hypericum perforatum* - herbal treatment for depression);
- ciclosporin (used in transplant patients);
- gestodene (used in some birth control pills or for treating symptoms of menopause);
- 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 (to treat angina pectoris);
- certain types of medicines to treat anxiety, depression, schizophrenia or other psychoses, (such as imipramine, ziprasidone, thioridazine, pimozide, sertindole);
- anti-malarial medicine (such as mefloquine or halofantrine);
- erythromycin IV (an antibiotic);
- pentamidine (an antiparasitic medicine);
- cisapride (against gastro-oesophageal reflux).

- Some types of diuretics (water tablets) which may cause a decrease in potassium levels, such as furosemide, hydrochlorothiazide, indapamide.

HOW TO TAKE CORALAN®:

Do not share medicines prescribed for you with any other person.
Always take **Coralan®** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

If you are being treated for stable angina pectoris:

The starting dose should not exceed one tablet of **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 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 starting dose is one tablet of **Coralan®** 5 mg twice daily increasing if necessary to one tablet of **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 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.

Coralan® should be taken during meals.
If you have the impression that the effect of **Coralan®** is too strong or too weak, talk to your doctor or pharmacist.
Coralan® is not intended for use in children and adolescents younger than 18 years.

Method of administration:
Swallow your tablet(s) with a glass of water, in the morning and in the evening.

If you take more Coralan® than you should:
A large dose of **Coralan®** could make you feel dizzy, breathless or tired because your heart rate slows down too much and your blood pressure decreases.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take Coralan®:
If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.
Do not take a double dose to make up for the forgotten individual doses.

Effects when treatment with Coralan® is stopped:
You should discuss with your doctor before stopping this medicine.
If you think that the effect of **Coralan®** is too strong or too weak for you, tell your doctor or pharmacist.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

POSSIBLE SIDE EFFECTS:
Coralan® can have side effects.
Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Frequent:

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.

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.

Abnormal perception of heartbeat, increased blood pressure, headache, dizziness and blurred vision (cloudy vision).

Less Frequent:

Palpitations and cardiac extra beats, feeling sick (nausea), constipation, diarrhoea, abdominal pain, spinning sensation (vertigo), difficulty breathing (dyspnoea), muscle cramps and changes in laboratory parameters: 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), 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, urticaria, itching, skin reddening, feeling unwell, irregular heartbeats.

HOW TO STORE CORALAN®:

Keep all medicine out of the reach of children.

Store at or below 30 °C.

Do not use after the expiry date on the blister.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

PRESENTATION:

Aluminium/PVC blister strips with 56 tablets in a carton.

IDENTIFICATION OF THE MEDICINE:

Coralan® 5 mg: Salmon-coloured, rod shaped, film-coated tablets scored on both edges, engraved with "5" on one face and  on the other face.

Coralan® 7,5 mg: salmon-coloured, triangular, film-coated tablet engraved with "7,5" on one face and  on the other face.

REGISTRATION NUMBER:

Coralan® 5 mg: A39/7.1.4/0410

Coralan® 7,5 mg: A39/7.1.4/0411

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE:

Servier Laboratories South Africa (Pty) Ltd
Building Number 4
Country Club Estate
21 Woodlands Drive
Woodmead
2191

DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET:

Date on the registration certificate: 9 December 2008

Date of the most recent amendment approved by Council: 1 March 2013 (full revision)

Namibia Details

Coralan 5 mg: 08/7.6/0163 (NS2)

Coralan 7,5 mg: 08/7.6/0162 (NS2)