

CORALAN

ivabradine (as the hydrochloride)
5mg & 7.5mg film coated tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CORALAN[®] (Coh'-rah-lan). It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the benefits they expect CORALAN[®] will have for you against the risks of you taking it.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine - you may need to read it again.

What CORALAN[®] is

The name of your medicine is CORALAN[®]. The medicine contains the active ingredient ivabradine (I-vab'-rah-deen).

What CORALAN[®] is used for

CORALAN[®] is used for *stable* angina.

Stable angina typically occurs when you exert yourself, and is usually relieved with medication or rest. CORALAN[®] relieves *stable* angina by lowering the heart rate.

Angina is a pain or uncomfortable feeling in the chest. This pain or feeling can also spread to the arms and neck and sometimes also to the shoulders and back. Angina is caused by too little blood and oxygen getting to the heart. CORALAN[®] is not for the relief of a *sudden* attack of angina. Your doctor will have given you other medication to treat this.

CORALAN[®] can only be obtained with a doctor's prescription.

There is no evidence that CORALAN[®] is addictive.

Ask your doctor if you have any questions

about why CORALAN[®] has been prescribed for you.

Before you take CORALAN[®]

When you must not take it

There are some people who should not take CORALAN[®]. Please read the lists below. If you think any of these situations apply to you, or you have any questions, please consult your doctor or pharmacist.

Do not use CORALAN[®] if:

- You have an allergy to ivabradine hydrochloride, the active substance in CORALAN[®], or to any of the other ingredients listed at the end of this leaflet;
- You have disturbances of heart rhythm; a "sick sinus syndrome" or sino-atrial block;
- You have an artificial pacemaker;
- You have 3rd degree Atrioventricular (AV) block ;
- You have a resting heart rate below 60 beats per minute (bpm) prior to treatment ;
- You have severe heart failure. (Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. It does not mean that the heart stops working);
- You have very low blood pressure ;
- You have *unstable* angina. *Unstable* angina is a pain or uncomfortable feeling in the chest that lasts longer than a few minutes or occurs with rest, and may not be relieved with medication;
- You have cardiogenic shock which is a sudden and severe drop in blood pressure and blood flow through the body because the heart is not pumping normally;
- You are having a heart attack;
- You are taking any of the following medications: ketoconazole, an oral antifungal therapy; antibiotics of the macrolide class, including azithromycin, clarithromycin, erythromycin and roxithromycin; ciclosporin, used to prevent rejection following transplants; gestodene and anti-retroviral drugs such as medicines to treat HIV infections;
- You have severe liver disease;
- You suffer from Hypertrophic Cardiomyopathy (HOCM);
- You are pregnant or breastfeeding.

Do not use CORALAN[®] to treat any other complaints unless your doctor says it is safe.

Do not give this medicine to anyone else.

Do not use CORALAN[®] after the expiry date (EXP) printed on the pack. It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

Do not use CORALAN[®] if the packaging is torn or shows signs of tampering. If the packaging is damaged when you first receive the product, return it to your pharmacist.

You must tell your doctor if

Tell your doctor immediately if:

- You are pregnant;
- You have a very slow heart beat (less than 60 beats per minute);
- You have low blood pressure;
- You have had a recent stroke;
- You have moderate or severe heart failure;
- You are allergic to any other medicines or any foods, dyes or preservatives;
- You have severe liver disease;
- You have moderate or severe kidney disease;
- You have an eye condition called 'retinitis pigmentosa', a condition that affects the light sensitive cells on the inner portion of the eye.

Your doctor may want to take special precautions if you have any of these conditions.

If you have not told your doctor about any of these things, tell them before you start using CORALAN[®].

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines. This includes medicines purchased from pharmacies, health food shops and supermarkets as well as prescribed medicines.

Some medicines and foods can interfere with the action of CORALAN[®] by increasing or decreasing its effect. **Some medicines should not be taken at all.**

These include:

- Grapefruit and grapefruit juice;
- Antibiotics of the macrolide class, including azithromycin, clarithromycin, erythromycin and roxithromycin;
- Cyclosporin, used to prevent rejection following transplants;
- Ketoconazole, an oral antifungal therapy;
- Gestodene;
- Medicines to treat HIV infections;
- Rifampicin (an antibiotic);
- Barbiturates (for difficulty sleeping or epilepsy);
- Phenytoin (for epilepsy);

- Beta-blockers (like atenolol, propranolol, metoprolol, etc, for high blood pressure, heart rhythm disorders, or angina pectoris);
- Quinidine, disopyramide, ibutilide, sotalol (to treat heart rhythm disorders);
- Certain types of medicines to treat depression (such as imipramine);
- Certain types of medicines to treat anxiety, schizophrenia or other psychoses (such as phenothiazines and thioridazine);
- Amiodarone (for heart rhythm disorders);
- Some medicines of the calcium channel blocker class, including diltiazem and verapamil;
- Some herbal remedies such as St John's Wort.

How to take CORALAN[®]

Follow all directions given to you by your doctor and pharmacist carefully. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

The usual dose is one tablet taken twice a day i.e. in the morning and at night, to be taken by mouth. Swallow the tablet whole with a glass of water.

CORALAN should be taken with food.

The dose of CORALAN[®] you need will be decided and adjusted by your doctor. In all cases, strictly follow your doctor's directions.

If you think that the effect of CORALAN[®] is too strong or too weak, talk to your doctor or pharmacist.

If you forget to take CORALAN[®]

If you forget to take a dose, take the next dose at your normal time.

Do not take a double dose next time.

If you take more CORALAN[®] than you should (overdose)

If you think that you or anyone else may have taken too much CORALAN[®], immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to the Accident & Emergency Department at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The general effects of taking an overdose of this treatment is a very slow heart beat. You may feel breathless or tired.

If you have this symptom when you take CORALAN[®], tell your doctor.

While you are taking CORALAN[®]

Follow your doctor's instructions about how many tablets to take, and when to take them. If you do not follow your doctor's instructions, you may not get the benefits from treating your angina.

Tell your doctor if the symptoms persist despite taking the treatment or if you think that the effect is too strong.

Tell your doctor well in advance of any expected hospitalisation or surgery. If you go to hospital unexpectedly, tell the doctor who admits you that you are using CORALAN[®].

Tell all doctors, dentists or pharmacists who treat you that you are using CORALAN[®].

If you discover you are pregnant while taking CORALAN[®], tell your doctor immediately.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CORALAN[®].

CORALAN[®] helps most people with symptoms of angina, but it may have unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this explanation of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following side effects and if they worry you.

The most frequently reported side effect is temporary visual symptoms. Some patients taking CORALAN may see bright spots of light particularly when moving quickly

between dim and bright lighting conditions. Blurred vision may also occur.

These visual symptoms are usually mild and appear in the first two months of treatment, and then disappear as treatment continues. Tell your doctor or pharmacist if they bother you.

Be careful when driving or operating machinery in situations where there may be sudden changes in dim to bright lighting.

Another common side effect is bradycardia (slow heart beat).

Tell your doctor if you notice anything else that makes you feel unwell.

After taking CORALAN[®]

Storage

Keep the medicine where children cannot reach it.

A locked cupboard at least one and-a-half metres above floor level is a good place to store medicines.

Heat and dampness can reduce the quality of medicines. Keep CORALAN[®] in a cool dry place where the temperature stays below 30°C, but not in the fridge or freezer.

Keep your tablets in their blister pack until it is time to take them.

If you take the tablets out of the box or the blister pack they may not keep well.

Disposal

If your doctor tells you to stop taking CORALAN[®] or the tablets have passed their expiry date, return the unused medicines to your pharmacist.

Product description

What it looks like

CORALAN[®] 5mg: salmon-pink coloured, rod-shaped, film-coated tablet scored on both edges, engraved with "5" on one face and the Servier logo on the other.

CORALAN[®] 7.5mg: salmon-pink coloured, triangular, film-coated tablet engraved with "7.5" on one face and the Servier logo on the other.

CORALAN[®] 5mg and CORALAN[®] 7.5mg tablets are supplied in a blister strip, in packs containing 14 or 56 tablets.

Ingredients

Each CORALAN[®] 5mg tablet contains 5mg of ivabradine, as the hydrochloride salt.

Each CORALAN[®] 7.5mg tablet contains 7.5mg of ivabradine, as the hydrochloride salt

CORALAN[®] also contains the following inactive ingredients:

Tablet Core:

Lactose, magnesium stearate, maize starch, maltodextrin, silica (colloidal anhydrous).

Film-coating:

Hypromellose, titanium dioxide (E 171), macrogol 6000, glycerol, magnesium stearate, yellow iron oxide (E 172), red iron oxide (E 172).

Manufacturer and sponsor

CORALAN[®] is a product discovered by Servier Research International.



It is distributed in Australia by:

Servier Laboratories (Australia) Pty Ltd

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8 Cato Street

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Australia

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