Package leaflet: information for the patient

Procoralan 5 mg film-coated tablets
Procoralan 7.5 mg film-coated tablets
ivabradine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Procoralan is and what it is used for

Procoralan (ivabradine) is a heart medicine used to treat:
- Symptomatic stable angina pectoris (which causes chest pain) 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. It is also used 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 over or equal to 75 beats per minute. It is used in combination with standard therapy, including beta-blocker therapy or when beta-blockers are contraindicated or not tolerated.

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. The most common symptom of angina is chest pain or discomfort.

About chronic heart failure :
Chronic heart failure is a heart disease which happens when your 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 Procoralan work?
The specific heart rate lowering action of ivabradine helps:
- to control and reduce the number of angina attacks by lowering heart’s need for oxygen,
- to improve the heart functioning and vital prognosis in patients with chronic heart failure.

2. What you need to know before you take Procoralan

Do not take Procoralan
- if you are allergic to ivabradine or any of the other ingredients of this medicine (listed in section 6);
- 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 (sick sinus syndrome, sino-atrial block, 3rd degree AV-block);
- if you are having a heart attack;
- if you suffer from very low blood pressure;
- 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 heartbeat is exclusively imposed by your 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 nelfinavir, ritonavir) or nefazodone (medicine to treat depression) or diltiazem, verapamil (used for high blood pressure or angina pectoris);
- 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 breast-feeding.

Warnings and precautions
Talk to your doctor or pharmacist before taking Procoralan:
- 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 straight away to your doctor before or while taking Procoralan.

Children
Do not give this medicine to children and adolescents younger than 18 years. Available data are insufficient in this age group.

Other medicines and Procoralan
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Make sure to tell your doctor if you are taking any of the following medicines, as a dose adjustment of Procoralan or monitoring should be required:
- 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)
- QT prolonging medicines to treat either heart rhythm disorders or other conditions :
  - quinidine, disopyramide, ibutilide, sotalol, amiodarone (to treat heart rhythm disorders)
  - bepridil (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)
- 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).

Procoralan with food and drink
Avoid grapefruit juice during treatment with Procoralan.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
Do not take Procoralan if you are pregnant or are planning to have a baby (see "Do not take Procoralan").
If you are pregnant and have taken Procoralan, talk to your doctor.
Do not take Procoralan if you are able to become pregnant unless you use reliable contraceptive measures (see "Do not take Procoralan").
Do not take Procoralan if you are breast-feeding (see "Do not take Procoralan"). Talk to your doctor if you are breast-feeding or intending to breast-feed as breast-feeding should be discontinued if you take Procoralan.

Driving and using machines
Procoralan 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.

Procoralan 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.

3. How to take Procoralan

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Procoralan should be taken during meals.
Procoralan 5 mg tablet can be divided into equal doses.

<u>If you are being treated for stable angina pectoris</u>
The starting dose should not exceed one tablet of Procoralan 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 aged 75 years or more), your doctor may prescribe half the dose i.e., one half 5 mg tablet of Procoralan 5 mg (corresponding to 2.5 mg ivabradine) in the morning and one half 5 mg tablet in the evening.

<u>If you are being treated for chronic heart failure</u>
The usual recommended starting dose is one tablet of Procoralan 5 mg twice daily increasing if necessary to one tablet of Procoralan 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 aged 75 years or more), your doctor may prescribe half the dose i.e., one half 5 mg tablet of Procoralan 5 mg (corresponding to 2.5 mg ivabradine) in the morning and one half 5 mg tablet in the evening.

If you take more Procoralan than you should:
A large dose of Procoralan 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 Procoralan:
If you forget to take a dose of Procoralan, 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 Procoralan.

If you stop taking Procoralan:
As the treatment for angina or chronic heart failure is usually life-long, you should discuss with your doctor before stopping this medicinal product.
If you think that the effect of Procoralan 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.

4. Possible side effects

Like all medicines, this medicine can cause 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, 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 (may affect up to 1 in 10 people)
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.

Other side effects have also been reported:

Common (may affect up to 1 in 10 people)
Irregular rapid contraction of the heart (atrial fibrillation), abnormal perception of heartbeat (bradycardia, ventricular extrasystoles, 1st degree AV block (ECG prolonged PQ interval)), uncontrolled blood pressure, headache, dizziness and blurred vision (cloudy vision).

Uncommon (may affect up to 1 in 100 people)
Palpitations and cardiac extra beats, feeling sick (nausea), constipation, diarrhoea, abdominal pain, spinning sensation (vertigo), difficulty breathing (dyspnoea), muscle spasms, 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 (may affect up to 1 in 1,000 people)
Urticaria, itching, skin reddening, feeling unwell.

Very rare (may affect up to 1 in 10,000 people)
Irregular heart beats (2nd degree AV block, 3rd degree AV block, sick sinus syndrome).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

United Kingdom (Northern Ireland)
Yellow Card Scheme
website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Procoralan

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Content of the pack and other information

What Procoralan contains
- The active substance is ivabradine (as hydrochloride).

  Procoralan 5 mg film-coated tablets:

  each film-coated tablet contains 5 mg ivabradine (as hydrochloride).

  Procoralan 7.5 mg film-coated tablets:

  each film-coated tablet contains 7.5 mg ivabradine (as hydrochloride).

- The other ingredients are:
  - *tablet core*: lactose monohydrate, magnesium stearate (E 470 B), maize starch, maltodextrin, colloidal anhydrous silica (E 551),
  - *film coating*: hypromellose (E 464), titanium dioxide (E 171), macrogol (6000), glycerol (E 422), magnesium stearate (E 470 B), yellow iron oxide (E 172), red iron oxide (E 172).

What Procoralan looks like and contents of the pack
Procoralan 5 mg tablets are salmon-coloured, oblong film-coated tablets scored on both sides, engraved with "5" on one face and  on the other.
Procoralan 7.5 mg tablets are salmon-coloured, triangular, film-coated tablets engraved with "7.5" on one face and  on the other.

The tablets are available in calendar packs (Aluminium/PVC blisters) of 14, 28, 56, 84, 98, 100 or 112 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Les Laboratoires Servier
50, rue Carnot
92284 Suresnes cedex - France

Manufacturer

Servier (Ireland) Industries Ltd
Gorey Road
Arklow - Co. Wicklow
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

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Detailed information on this medicine is available on the European Medicines Agency web site:
http://www.ema.europa.eu