PACKAGE LEAFLET: INFORMATION FOR THE USER

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.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT PROCORALAN IS AND WHAT IT IS USED FOR

Procoralan (ivabradine) is a heart medicine used to treat stable angina pectoris which causes chest pain.
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 and whose heart rate is too high (over 60 beats per minute).

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.

How does Procoralan work?
Procoralan 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 Procoralan helps to control and reduce the number of angina attacks.

2. BEFORE YOU TAKE PROCORALAN

Do not take Procoralan
- if you are allergic (hypersensitive) to ivabradine or any of the other ingredients of Procoralan (see "further information" for a list of all ingredients);
- if your resting heart rate before treatment is too slow (below 60 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;

- if you suffer from unstable angina (a severe form in which chest pain occurs very frequently and with or without exertion);
- if you suffer from severe heart failure (when your heart fails to work properly);
- if you have a 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) (see "Taking other medicines");
- if you are pregnant;
- if you are breast-feeding.

Take special care with 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),
- 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 have had a recent stroke (cerebral attack),
- if you suffer from mild to moderate low blood pressure,
- if you suffer from chronic heart failure (when your heart fails to work properly),
- 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
Procoralan is not intended for use in children and adolescents younger than 18 years.

Taking other medicines
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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:
- diltiazem, verapamil (used for high blood pressure or angina pectoris)
- 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)

Taking Procoralan with food and drink
Limit your consumption of grapefruit juice during treatment with Procoralan.

Pregnancy and breast-feeding
Do not take Procoralan if you are pregnant or planning a pregnancy (see "Do not take Procoralan").
If you are pregnant and have taken Procoralan, talk to your doctor.
Do not take Procoralan if you are breast-feeding (see "Do not take Procoralan").

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

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.

Important information about some of the ingredients of Procoralan
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 Procoralan exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. 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 elderly), 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.
Procoralan should be taken during meals.

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 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, Procoralan can cause side effects, although not everybody gets them.

The frequency of possible side effects listed below is defined using the following convention:
very common (affects more than 1 user in 10)
common (affects 1 to 10 users in 100)
uncommon (affects 1 to 10 users in 1,000)
rare (affects 1 to 10 users in 10,000)
very rare (affects less than 1 user in 10,000)
not known (frequency cannot be estimated from the available data)

Very common:
Luminous visual phenomena (brief moments of increased brightness, most often caused by sudden changes in light intensity).

Common:
Modification in the heart functioning (the symptoms are a slowing down of the heart rate), abnormal perception of heartbeat, headache, dizziness and blurred vision.

Uncommon:
Palpitations and cardiac extra beats, feeling sick (nausea), constipation, diarrhoea, 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).

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PROCORALAN

Keep out of the reach and sight of children.

Do not use Procoralan 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Procoralan contains
- The active substance is ivabradine (as hydrochloride).
  Procoralan 5 mg: one film-coated tablet contains 5 mg ivabradine (equivalent to 5.390 mg ivabradine as hydrochloride).
  Procoralan 7.5 mg: one film-coated tablet contains 7.5 mg ivabradine (equivalent to 8.085 mg ivabradine as hydrochloride).
- The other ingredients in the tablet core are: lactose monohydrate, magnesium stearate (E 470 B), maize starch, maltodextrin, colloidal anhydrous silica (E 551), and in the tablet 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 and Manufacturer:

Marketing Authorisation Holder:
Les Laboratoires Servier
22 rue Garnier

92200 Neuilly sur Seine - France

Manufacturer:
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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