PATIENT GUIDE

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

Procoralan® 5 & 7.5 mg (ivabradine)

This guide provides you with recommendations for a safe use of **Procoralan® (**ivabradine) to avoid side effects and advice on what to do if such side effects occur during treatment.

Ask your doctor for any further information.

Procoralan® (ivabradine) is a heart medicine used to treat Chronic heart failure in adult patients.
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.

In order to optimize your medical care, follow the recommendations of your doctor regarding the intake of Procoralan® treatment (dose, duration of treatment, associated follow up such as scheduled appointments,…..).

How to take Procoralan®

Always take this medicine exactly as your doctor, health care provider or pharmacist has told you. Check with your doctor, health care provider or pharmacist if you are not sure.

Procoralan® should be taken during meals.

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 or health care provider 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 or health care provider 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 or health care provider 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®.

Do not take Procoralan®

- if you are **allergic to ivabradine or any of the other ingredients** of this medicine ;
- 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**;
- 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 heart beat 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.**

Take special care with Procoralan®

Talk to your doctor, health care provider 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 or health care provider before or while taking Procoralan®.

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.
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.

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, abnormal perception of heartbeat, 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 cramps, 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), 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.

If you get any side effects, talk to your doctor, health care provider or pharmacist. This includes any possible side effects not listed in this Guide. You can also report side effects directly via the national reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

For further information please read the patient leaflet.
If you have any further questions on the use of this medicine, ask your doctor, health care provider or pharmacist.

Call for reporting

As a reminder, there is a need to report any suspected adverse reactions to the National Pharmacovigilance and Drug Safety Centre or Pharmacovigilance department in Servier, according to the following;

Saudi Food and Drug Authority Call Center: 19999
By e-mail: npc.drug@sfda.gov.sa
Or by online: https://ade.sfda.gov.sa/

Pharmacovigilance department in Servier:
LPV: Ghaida ALAMMARI
E-mail: pv.sa1@servier.com
Tel.: +966 (0)11 25 22 330 Extn 304
Mobile: +966 (0)5 55 07 08 17

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