Procard® 150 & 300mg

Irbesartan
Film Coated Tablets

COMPOSITION

Procard® 150 mg: Each film coated tablet contains 150 mg Irbesartan.
Procard® 300 mg: Each film coated tablet contains 300 mg Irbesartan.
Excipients: Lactose monohydrate (Pharmatose 200M), Silica colloidal anhydrous (Aerosil 200), Cellulose microcrystalline (Avicel pH105), Croscarmellose sodium (Ac-Di-Sol), Hypromellose (Pharmacoat 603), Starch pregelatinized (Starch 1500), Cellulose microcrystalline (Avicel pH 102), Magnesium Stearate, Purified water, Opadry II white OY-L-28900.

DESCRIPTION & INDICATIONS

Irbesartan belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body which binds to receptors in blood vessels causing them to tighten. This results in an increase in blood pressure. Irbesartan prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax and the blood pressure to lower. Irbesartan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Procard is used:

- To treat high blood pressure (essential hypertension)
- To protect the kidney in patients with high blood pressure, type 2 diabetes and laboratory evidence of impaired kidney function.

CONTRAINDICATIONS

Do not take Procard:

- If you are allergic (hypersensitive) to Irbesartan or any other ingredients of **Procard®**.
- During the last 6 months of pregnancy (See: Pregnancy & Breast-feeding).
- If you are breast-feeding.
- If you have kidney impairment or diabetes the combination of Aliskiren and Irbesartan is stricktly contraindicated for you.
- In a small number of patients (mostly with heart failure) there may still be a medical need to combine two classes of medicines that act on the renin-angiotensin system. When this is considered absolutely necessary, it will be carried out under specialist supervision with close monitoring of kidney function, fluid and salt balance and blood pressure.

Irbesartan should not be given to children and adolescents (under 18 years).

PRECAUTIONS

Tell your doctor if any of the following apply to you:

- If you get excessive vomiting or diarrhoea
- If you suffer from kidney problems
- If you suffer from heart problems
- If you receive Irbesartan for diabetic kidney disease. In this case your doctor may perform regular blood tests, especially for measuring blood potassium levels in case of poor kidney function.
- If you are going to have an operation (surgery) or be given anaesthetics.

You must tell your doctor if you think you are (or might become) pregnant. Irbesartan is not recommended in early pregnancy, and may cause serious harm to your baby after 3 months of pregnancy (See: Pregnancy & Breast-feeding).
Procard® contains lactose. If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicine.
Use in Children: This medicinal product should not be used in children and adolescents because the safety and efficacy have not yet been fully established.

INTERACTIONS

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

- Restrictions on combining an ARB (like Irbesartan) with an ACE-inhibitor was associated with an increased risk of hyperkalaemia, kidney damage, low blood pressure.
- Combination of medicines from any two of these classes is not recommended and, in particular, patients with diabetes-related kidney problem should not be given an ARB with an ACE-inhibitor.

Irbesartan does not usually interact with other edicines. You may need to have blood checks if you take:

- Potassium supplements
- Salt substitutes containing potassium
- Potassium-sparing medicines (such as certain diureticsa)
- Medicines containing lithium.

If you take certain painkillers, called non-steroidal anti-inflammatory drugs, the effect of Irbesartan may be reduced.
Taking Irbesartan with food and drink
Ibesartan can be taken with or without food.

PREGNANCY AND BREAST-FEEDING

Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. usually, your doctor will advise you to take another medicine instead of **Procard®**, as Irbesartan is not recommended in early pregnancy, and may cause serious harm to your baby if it is used after 3 months of pregnancy. Appropriate antihypertensive drug must usually replace irbesartan before starting a pregnancy. The product should not be used during the 2nd and 3rd trimester of pregnancy, or while breast-feeding
Your doctor will normally advise you to stop taking irbesartan as soon as you know you are pregnant. If you become pregnant during therapy with irbe-

sartan, please inform and see your doctor without delay.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. **Procard®** is unlikely to affect your ability to drive or use machines. However, occasionally dizziness or weariness may occur during treatment of high blood pressure. If you experience these, talk to your doctor before attempting to drive or use machines.

HOW TO TAKE PROCARD

Always take **Procard®** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Method of administration

Procard® is for oral use. Swallow the tablets with a sufficient amount of fluid (e.g. one glass of water). You can take **Procard®** with or without food. Try to take your daily dose at about the same time each day. It is important that you continue to take **Procard®** until your doctor tells you otherwise.

Patients with high blood pressure

The usual dose is 150 mg once a day. The dose may later be increased to 300 mg once daily depending on blood pressure response.

Patients with high blood pressure and type 2 diabetes with kidney disease

In patients with high blood pressure and type 2 diabetes, 300 mg once daily is the preferred maintenance dose for the treatment of associated kidney disease.

The doctor may advise a lower dose, especially when starting treatment in certain patients such as those on haemodialysis, or those over the age of 75 years. The maximal blood pressure lowering effect should be reached 4-6 weeks after beginning treatment.

OVERDOSAGE

If you accidentally take too many tablets, contact your doctor immediately.

Children should not take Procard

Procard® should not be given to children under 18 years of age. If a child swallows some tablets, contact your doctor immediately.

If you forget to take Procard

If you accidentally miss a daily dose, just take the next dose as normal. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

POSSIBLE SIDE EFFECTS

Like all medicines, **Procard®** can cause side effects, although not everybody gets them. Some of these effects may be serious and may require medical attention.

As with similar medicines, rare cases of allergic skin reactions (rash, urticaria), as well as localised swelling of the face, lips and/or tongue have been reported in patients taking Irbesartan. If you get any of these symptoms or get short of breath, stop taking Procard and contact your doctor immediately.

The frequency of the side effects listed below is defined using the following convention:

- Very common: at least 1 in 10 patients or more
- Common: at least 1 in 100 and less than 1 in 10 patients
- Uncommon: at least 1 in 1000 and less than 1 in 100 patients

Side effects reported in clinical studies for patients treated with Irbesartan were:

Very common: if you suffer from high blood pressure and type 2 diabetes with kidney disease, blood tests may show an increased level of potassium.

Common: dizziness, feeling sick/vomiting, fatigue and blood tests may show raised levels of an enzyme that measures the muscle and heart function (creatine kinase enzyme). In patients with high blood pressure and type 2 diabetes with kidney disease, dizziness when getting up from a lying or sitting position, low blood pressure when getting up from a lying or sitting position, pain in joints or muscles and decreased levels of a protein in the red blood cells (haemoglobin) were also reported.

Uncommon: heart rate increased, flushing, cough, diarrhoea, indigestion/heartburn, sexual dysfunction (problems with sexual performance), chest pain. Some undesirable effects have been reported since marketing of Irbesartan.

Undesirable effects where the frequency is not known are: feeling of spinning, headache, taste disturbance, ringing in the ears, muscle cramps, pain in joints and muscles, abnormal liver function, increased blood potassium levels, impaired kidney function, and inflammation of small blood vessels mainly affecting the skin (a condition known as leukocytoclasticvamlitis).

Uncommon cases of jaundice (yellowing of the skin and/or whites of the eyes) have also been reported.

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.

STORAGE

Store below 30° C

Do not use **Procard®** after the expiry date which is stated on the carton and blister.

NATURE & CONTENTS OF CONTAINER:

Procard® 150 mg is packaged in PVC/PVDC aluminum blisters placed into cardboard boxes containing 28 film coated tablets.

Procard® 300 mg is packaged in PVC/PVDC aluminum blisters placed into cardboard boxes containing 28 film coated tablets.

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This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicament out of the reach of children.

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