PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

IRBECARD 75 mg, 150 mg and 300 mg film-coated tablets

Irbesartan

Excipient with known effect:

IRBECARD 75 mg: 13,0 mg of lactose monohydrate per film-coated tablet

IRBECARD 150 mg: 26,0 mg of lactose monohydrate per film-coated tablet

IRBECARD 300 mg: 52,0 mg of lactose monohydrate per film-coated tablet

Read all of this leaflet carefully before you start taking IRBECARD

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- IRBECARD has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What IRBECARD is and what it is used for

IRBECARD contains the active ingredient irbesartan, which belongs to a group of medicines called angiotensin II receptor blockers (ARBs).

It is used to treat high blood pressure (essential hypertension) and for the protection of the kidney in patients with high blood pressure, type 2 diabetes and laboratory evidence of impaired kidney function.

Your doctor may prescribe you IRBECARD either alone or in combination of other medicines.

2. What you need to know before you take IRBECARD

Do not take IRBECARD:

- if you are hypersensitive (allergic) to irbesartan, or any of the other ingredients of IRBECARD listed in section 6 of this leaflet.
- if you have a history of angioedema (swelling around your face, throat or tongue) related to previous therapy with ARBs or angiotensin converting enzyme inhibitors (ACEIs) (used to treat high blood pressure).
- if you have hereditary angioedema (swelling around your face, throat or tongue).
- if you have hypertrophic obstructive cardiomyopathy (HOCM) (a heart disease characterised by the obstruction of blood flow and thickening of heart tissue).
- if you have severe kidney impairment.
- if you have kidney impairment and are using fluoroquinolones (used to treat bacterial infections).
- if you have renal artery stenosis (kidney problems with reduced blood supply to your kidney) or a transplanted kidney.
- if you have aortic stenosis (a decrease in blood supply flow through the aortic artery).
- if you are taking potassium-sparing diuretics (such as spironolactone, triamterene, amiloride).
- if you have porphyria.

- if you are taking lithium.
- if you are pregnant or breastfeeding.
- If you are taking medicines containing aliskiren (used to treat high blood pressure).

Warnings and precautions:

Tell your doctor or health care provider before taking IRBECARD:

- if you get excessive vomiting or diarrhoea (leading to sodium/volume depletion).
- if you suffer from kidney problems.
- If you are 65 years or older.
- if you suffer from heart problems.
- if you are taking medicines to lower blood pressure (such as an ACE inhibitor).
- if you have diabetic kidney disease. Your doctor may perform regular blood tests, especially to measure the levels of potassium in your blood in the event of poor kidney function.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (such as potassium) in your blood at regular intervals.

Children and adolescents

IRBECARD should not be used in children and adolescents as the safety and efficacy have not been established.

Other medicines and IRBECARD

Always tell your health care provider if you are taking any other medicine (this includes complementary or traditional medicines).

Tell your doctor if you are using other medicines to reduce your blood pressure. Your doctor may adjust your dose or take other precautions.

Do not take IRBECARD with fluoroquinolones (used to treat bacterial infections), such as levofloxacin, ciprofloxacin or moxifloxacin.

You may need to have your blood checked regularly if you take:

- potassium supplements or medicines that may increase potassium levels in the blood (such as heparin).
- medicines containing lithium.
- non-steroidal anti-inflammatory medicines (NSAIDs); (used to treat pain, fever and inflammation).
- diuretic medicines ('water pills' used to get rid of excess water).

IRBECARD with food, drink and alcohol

No information of relevance available.

Pregnancy and breastfeeding

If you are taking IRBECARD, you should use effective contraception.

If you are pregnant or breastfeeding, think you might be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking IRBECARD.

Your doctor will change your treatment with IRBECARD to an alternative therapy which is safe to use during pregnancy and breastfeeding.

You should not use IRBECARD if you are pregnant or breastfeeding (see **Do not take IRBECARD).**

Driving and using machines

Your ability to drive or use machines may be affected by side effects, such as dizziness and tiredness. Do not drive a vehicle or operate machinery until you know how IRBECARD affects you.

IRBECARD contains sugar (lactose monohydrate)

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking IRBECARD.

3. How to take IRBECARD

Do not share medicines prescribed for you with any other person.

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

The usual dose is 150 mg once a day.

Your doctor may decide to increase your daily dose to 300 mg depending on your blood pressure.

Your doctor will tell you how long your treatment with IRBECARD will last. Do not stop treatment early because your blood pressure may increase again.

If you have the impression that the effect of IRBECARD is too strong or too weak, tell your doctor or pharmacist.

If you take more IRBECARD than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre.

If you forget to take IRBECARD

If you forget to take a dose, take it as soon as you remember unless it is nearly time to take your next dose. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

IRBECARD can have side effects.

Not all side effects reported for IRBECARD are included in this leaflet. Should your general health worsen or you experience any untoward effects while taking IRBECARD, please consult your health care provider for advice.

If any of the following happens, stop taking IRBECARD and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to IRBECARD. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- yellowing of the eyes or skin, also called jaundice or hepatitis,
- decreased kidney function or kidney failure (causing drowsiness, shortness of breath, fatigue, confusion, nausea, fits, passing less urine than is normal for you),
- too high levels of potassium in your blood (causing abnormal or slow heart rate, low blood pressure, cramps, weakness),
- bleeding or bruising more easily than normal,
- changes in the way your heart beats,
- leukocytoclastic vasculitis (causing rash, joint pains and increasing size of lymph nodes).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- headache or dizziness

- nausea (feeling sick) or vomiting (being sick)
- feeling tired
- dizziness or lightheadedness when getting up from a lying or sitting position
- muscle pain
- increases in blood levels of creatine kinase (enzyme that measures the muscle and heart function)
- decrease in level of haemoglobin (protein in red blood cells).

Less frequent side effects:

- changes in liver function
- changes in sexual function
- flushing
- cough
- diarrhoea
- indigestion or heartburn
- chest pain.

The following side effects have been reported with unknown frequency:

- vertigo (sensation of spinning or swaying) or tinnitus (ringing in the ears)
- pain in a joint
- pain in a muscle or group of muscles or muscle cramps
- distortion of the sense of taste
- abnormal physical weakness or lack of energy

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get 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 to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

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

5. How to store IRBECARD

Store at or below 30°C.

Keep the blisters in the outer carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date printed on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What IRBECARD contains

The active substance in IRBECARD is irbesartan.

IRBECARD 75 mg: Each film-coated tablet contains 75 mg irbesartan.

IRBECARD 150 mg: Each film-coated tablet contains 150 mg irbesartan.

IRBECARD 300 mg: Each film-coated tablet contains 300 mg irbesartan.

The other ingredients in IRBECARD:

Microcrystalline cellulose, pregelatinised starch, lactose monohydrate, poloxamer 188, croscarmellose sodium, magnesium stearate, opadry white.

What IRBECARD looks like and contents of the pack

IRBECARD 75 mg: A white to off-white, oblong, biconvex, film-coated tablet.

IRBECARD 150 mg: A white to off-white, oblong, biconvex film-coated tablet with score line and 'G' embossed on one side and plain on the other side.

IRBECARD 300 mg: A white to off-white, oblong, biconvex film-coated tablet with score line.

The film-coated tablets are packed in PVC/PVDC/ Aluminium foil blisters strips. The blister strips are packed in cartons containing 28, 30 tablets.

Not all pack sizes are marketed at any one time.

Holder of certificate of registration

Smart Pharmaceuticals (Pty) Ltd

247 Voortrekker Road

Kraaifontein, Cape Town

7570

This leaflet was last revised in

28 February 2022

Registration numbers

IRBECARD 75 mg: 47/7.1.3/0732

IRBECARD 150 mg: 47/7.1.3/0733

IRBECARD 300 mg: 47/7.1.3/0734

IRB/C/PIL/A