PATIENT INFORMATION LEAFLET

Scheduling status

S3

CO-IRBECARD 150/12,5 mg tablets

CO-IRBECARD 300/12,5 mg tablets

CO-IRBECARD 300/25 mg tablets

Irbesartan and hydrochlorothiazide

Contains sugar:

CO-IRBECARD 150/12,5 mg tablets – 26,0 mg lactose monohydrate per tablet

CO-IRBECARD 300/12,5 mg – 52,0 mg lactose monohydrate per tablet

CO-IRBECARD 300/25 mg – 52,0 mg lactose monohydrate per tablet

Read all of this leaflet carefully before you start taking CO-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.
- CO-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 CO-IRBECARD is and what it is used for

CO-IRBECARD tablets contain a combination of two active substances, irbesartan and hydrochlorothiazide.

CO-IRBECARD belongs to a group of medicines known as angiotensin II receptor blockers (ARBs). CO-IRBECARD prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax and the blood pressure to lower.

Hydrochlorothiazide is one of a group of medicines (called thiazide diuretics) that causes increased urine output and so causes a lowering of blood pressure.

CO-IRBECARD is used in the treatment of high blood pressure (hypertension)

2. What you need to know before you take CO-IRBECARD

Do not take CO-IRBECARD

- if you are hypersensitive (allergic) to irbesartan or hydrochlorothiazide or any other sulfonamide-derived medicines or any other ingredients of CO-IRBECARD (see section 6)
- 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): You must never again be given these medicines
- if you have hereditary angioedema (swelling around your face, throat or tongue)
- if you have heart disease characterised by obstruction of blood flow and thickening of heart tissue (hypertrophic obstructive cardiomyopathy)
- if you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis) or a transplanted kidney
- if you have a decrease in blood supply flow through the aortic artery (aortic stenosis)

- if you have porphyria
- if you have Addison's disease
- if you do not urinate or have severe kidney problems
- if you have kidney problems and are taking fluoroquinolones (a class of antibiotics)
- if you are taking potassium-sparing diuretics (such as spironolactone, triamterene, amiloride)
- if you are taking medicine containing lithium
- if you are pregnant or breastfeeding
- if you are taking aliskiren-containing medicines

CO-IRBECARD should not be given to children or adolescents.

Warnings and precautions

Take special care with CO-IRBECARD

- if you get excessive vomiting or diarrhoea (sodium/volume-depleted patients)
- if you suffer from kidney problems or have a kidney transplant
- if you suffer from heart problems
- if you suffer from liver problems
- if you suffer from diabetes
- if you suffer from lupus erythematosus
- if you suffer from primary aldosteronism
- if you experience an increased sensitivity of the skin to the sun with symptoms of sunburn (such as redness, itching, swelling, blistering) occurring more quickly than normal
- if you have decrease in your vision or pain in one or both of your eyes while taking CO-IRBECARD. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye (glaucoma) and can happen within hours to a week of taking CO-IRBECARD. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you

can be at higher risk of developing this. You should discontinue CO-IRBECARD treatment and seek prompt medical attention.

- if you have had skin cancer or if you develop an unexpected skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking CO-IRBECARD.

If you are to undergo any surgery or receive anaesthetics you should make sure the doctor knows that you are taking CO-IRBECARD tablets.

Important information about some of the ingredients of CO-IRBECARD

CO-IRBECARD contains lactose. If you have been told by your doctor that you have intolerance to some sugars (e.g. lactose), contact your doctor before taking CO-IRBECARD.

Other medicines and CO-IRBECARD

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

Diuretic medicines such as the hydrochlorothiazide contained in CO-IRBECARD may have an effect on other medicines. Preparations containing lithium should not be taken with CO-IRBECARD.

Your doctor may need to change your dose and/or to take other precautions if you are taking an ACE-inhibitor (see “Do not take CO-IRBECARD” and “Warnings and precautions”).

Alcohol, babiturates or narcotics may increase the risk of low blood pressure.

Non-steroidal anti-inflammatory drugs (NSAIDs) may attenuate the antihypertensive effect or may lead to an increased risk of worsening of kidney function and an increase in serum potassium.

Fluoroquinolones may precipitate acute kidney injury.

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

- potassium supplements
- salt substitutes containing potassium
- potassium-sparing medicines (such as diuretics)
- medicines for the treatment of gout
- therapeutic vitamin D supplements or calcium salts
- medicines to control heart rhythm
- medicines for diabetes (oral agents or insulins)

Taking CO-IRBECARD with food and drink

- You can take CO-IRBECARD with or without food.
- Take the tablet with sufficient quantity of liquid (e.g. one glass of water).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking CO-IRBECARD.

You must tell your doctor if you think you are (or might become) pregnant. Your doctor should immediately stop your treatment and switch you over to a different class of medicine.

CO-IRBECARD should not be used in pregnancy as it may cause serious harm to your baby (see section “Do not take CO-IRBECARD”).

You should ensure adequate contraception while taking CO-IRBECARD if you are of childbearing age.

Safety has not been establish in breastfeeding. You should not breastfeed your baby if you are taking CO-IRBECARD (see section “Do not take CO-IRBECARD”).

Driving and using machines

CO-IRBECARD is unlikely to affect your ability to drive or use machines. However, occasionally dizziness or weariness may occur during treatment of high blood pressure. Do not drive or operate machinery until you are sure how CO-IRBECARD affects you. If you experience these symptoms, you should consult your doctor before attempting such activities.

3. How to take CO-IRBECARD

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

Always take CO-IRBECARD exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure.

The usual starting dose is CO-IRBECARD 150/12,5 mg once daily. Your doctor may increase your dose after 1 to 2 weeks of therapy to 300/12,5 mg once daily as needed to control your blood pressure.

CO-IRBECARD may be prescribed by your doctor when your previous treatment did not reduce your blood pressure enough. Your doctor will instruct you how to switch from the previous treatment to CO-IRBECARD.

CO-IRBECARD is for oral use. Swallow the tablets with a sufficient amount of fluid (e.g. one glass of water). You can take CO-IRBECARD 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 CO-IRBECARD until your doctor tells you otherwise.

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

Children should not take CO-IRBECARD.

CO-IRBECARD should not be given to children under 18 years of age.

If you take more CO-IRBECARD than you should

In the event of over-dosage, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre.

Signs and symptoms of overdosage may include dehydration and electrolyte depletion (hypokalaemia, hypochloraemia, hyponatraemia). If a cardiac glycoside (e.g. digoxin) or other anti-dysrhythmic medicines (e.g. sotalol) has also been administered, hypokalaemia may accentuate abnormal rhythm of heartbeat.

If you forget to take CO-IRBECARD

If you have missed a dose, take it as soon as you remember. Take the next tablet as normal. Do not take a double dose to make up for a forgotten tablet.

4. Possible side effects

CO-IRBECARD can have side effects.

Not all side effects reported for CO-IRBECARD are included in this leaflet. Should your general health worsen while taking CO-IRBECARD, please consult your doctor, pharmacist or other healthcare professional for advice.

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 think you are developing such a reaction or get short of breath, **stop taking CO-IRBECARD and seek immediate medical attention**.

Frequent side effects:

- nausea/vomiting
- abnormal urination
- fatigue
- dizziness (including when getting up from a lying or sitting position)
- headaches

- blood tests may show raised levels of an enzyme that measures the muscle and heart function (creatine kinase) or raised levels of substances that measure kidney function (blood urea nitrogen, creatinine).

Less frequent side effects:

- diarrhoea, dry mouth
- low blood pressure
- fainting
- heart rate increased
- flushing
- swelling
- muscle pain
- sexual dysfunction (problems with sexual performance)
- blood tests may show lowered levels of potassium and sodium in your blood.

Undesirable effects where the frequency is not known are: cough, indigestion, liver function abnormal and impaired kidney function, increased level of potassium in your blood and allergic reactions such as rash, hives, swelling of the face, lips, mouth, tongue or throat. Uncommon cases of jaundice (yellowing of the skin and/or whites of the eyes) have also been reported.

As for any combination of two active substances, side effects associated with each individual component cannot be excluded.

Side effects associated with irbesartan alone:

In addition to the side effects listed above, chest pain, extremity weakness, ECG abnormalities, itching have also been reported.

Side effects associated with hydrochlorothiazide alone:

Loss of appetite; stomach irritation; stomach cramps; constipation; jaundice (yellowing of the skin and/or whites of the eyes); inflammation of the pancreas characterised by severe upper stomach pain, often with nausea and vomiting; sleep disorders; depression; blurred vision; lack of white blood cells, fever; decrease in the number of platelets, decreased number of red blood cells (anaemia), dizziness and looking pale; kidney disease; lung problems including pneumonia or build-up of fluid in the lungs; increased sensitivity of the skin to the sun; inflammation of blood vessels; a skin disease characterized by the peeling of the skin all over the body; cutaneous lupus erythematosus, allergic reactions; weakness and muscle spasm; altered heart rate; reduced blood pressure after a change in body position; swelling of the salivary glands; high sugar levels in the blood; sugar in the urine; increases in some kinds of blood fat; high uric acid levels in the blood, which may cause gout.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. 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 CO-IRBECARD.

5. How to store CO-IRBECARD

Store all medicines out of reach of children.

Store at or below 25°C, in the original package. Keep blisters in the carton until required for use.

Do not store in a bathroom.

Do not use **CO-IRBECARD** after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste.

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 CO-IRBECARD contains

The active substances are irbesartan and hydrochlorothiazide.

CO-IRBECARD 150/12,5 mg tablets contain 150 mg of irbesartan and 12,5 mg hydrochlorothiazide.

CO-IRBECARD 300/12,5 mg tablets contain 300 mg of irbesartan and 12,5 mg hydrochlorothiazide.

CO-IRBECARD 300/25 mg tablets contain 300 mg of irbesartan and 25 mg hydrochlorothiazide.

The other ingredients are: Microcrystalline cellulose, pregelatinised starch, lactose monohydrate, poloxamer 188, croscarmellose sodium, magnesium stearate, opadry pink.

What CO-IRBECARD looks like and contents of the pack

CO-IRBECARD 150/12,5 mg: A light pink, oblong, biconvex film-coated tablet.

CO-IRBECARD 300/12,5 mg: A light pink, oblong, biconvex film-coated tablet.

CO-IRBECARD 300/25 mg: A red-brick, oblong, biconvex, film-coated tablet with a score-line. The score line on Co-Irbecard 300/25 mg tablet is non-functional, instead it is just for discrimination with other strengths.

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

Not all packing sizes may be marketed.

Holder of certificate of registration

Smart Pharmaceuticals (Pty) Ltd

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7570

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COI/C/PIL/A