Patient Information Leaflet for CO-IRBEWIN

Read all of this leaflet carefully before you start taking CO-IRBEWIN.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- CO-IRBEWIN 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.

SCHEDULING STATUS:

S3

PROPRIETARY NAME AND DOSAGE FORM

CO-IRBEWIN 150/12,5 (Tablets)

CO-IRBEWIN 300/12,5 (Tablets)

Irbesartan / Hydrochlorothiazide

WHAT CO-IRBEWIN CONTAINS

The active substances in CO-IRBEWIN tablets are irbesartan and hydrochlorothiazide.

CO-IRBEWIN 150/12,5: Each tablet contains 150 mg irbesartan and 12,5 mg hydrochlorothiazide.

CO-IRBEWIN 300/12,5: Each tablet contains 300 mg irbesartan and 12,5 mg hydrochlorothiazide.

The other inactive ingredients are: croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, silicon dioxide and a film-coating.

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WHAT CO-IRBEWIN IS USED FOR

CO-IRBEWIN belongs to a group of medicines known as angiotensin-II receptor antagonists or blockers (ARBs). CO-IRBEWIN 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 (so called thiazide diuretics) that causes increased urine output and so causes a lowering of blood pressure.

The two active ingredients in CO-IRBEWIN work together to lower blood pressure further than if either was given alone.

Your doctor measured your blood pressure and found it to be above the normal range for your age.

CO-IRBEWIN is used to treat high blood pressure.

BEFORE YOU TAKE CO-IRBEWIN

Do not take CO-IRBEWIN if:

- You have had an allergic reaction to irbesartan, any of the ingredients in CO-IRBEWIN or sulfonamide-derived medicines.
- You have a history of angioedema (swelling around your face, throat or tongue) related to previous therapy with ACE inhibitors or ARBs: You must never again be given these medicines.
- You have hereditary angioedema (swelling around your face, throat or tongue).

- You have heart disease characterised by obstruction of blood flow and thickening of heart tissue (hypertrophic obstructive cardiomyopathy).
- You have kidney problems where the blood supply to your kidney is reduced (renal artery stenosis) or a transplanted kidney.
- You have a decrease in blood supply flow through the aortic artery (aortic stenosis).
- You have porphyria.
- You have Addison's disease.
- You do not urinate or have kidney impairment.
- You are treated concomitantly with potassium sparing diuretics such as spironolactone, triamterene and amiloride.
- You are treated concomitantly with lithium.
- You are pregnant or breastfeeding.
- You have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren or called Angiotensin Converting Enzyme Inhibitors (ACEIs).
- You have kidney problems and are taking fluoroquinolones (used to treat bacterial infections) at the same time (see TAKING OTHER MEDICINES WITH CO-IRBEWIN).

CO-IRBEWIN should not be given to children.

Take special care with CO-IRBEWIN:

There are certain conditions, which you may have, or have had, which require special care before or while taking CO-IRBEWIN. Therefore, before taking CO-IRBEWIN, you should have told your doctor if you suffer from:

- excessive vomiting or diarrhoea
- kidney problems or are an elderly patient.
- heart problems
- liver problems
- diabetes
- lupus erythematosus
- a skin condition called psoriasis or a history of psoriasis
- or previously have had skin or lip cancer.

Talk to your doctor immediately if you develop:

- If you have changes in your vision or pain in one or both of your eyes while taking CO-IRBEWIN. This could be a sign that you are developing glaucoma, increased pressure in your eye(s). You should discontinue CO-IRBEWIN treatment and seek medical attention
- sensitivity to the sun or uv light
- an unexpected skin lesion during the treatment.

Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of non-melanoma skin and lip cancer.

Protect your skin from sun exposure and ultraviolet rays including indoor tanning, while taking CO-IRBEWIN.

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

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Hydrochlorothiazide contained in CO-IRBEWIN could produce a positive analytic result in an anti-doping test.

Pregnancy and Breastfeeding:

CO-IRBEWIN should not be used during pregnancy or if you are breastfeeding (see Before you take CO-IRBEWIN tablets).

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

Driving and using machinery:

CO-IRBEWIN is unlikely to affect your ability to drive or use machines. However, dizziness or weariness may occur during treatment of high blood pressure. If you experience these symptoms, you should consult your doctor before attempting such activities.

Important information about some of the ingredients of CO-IRBEWIN:

CO-IRBEWIN 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-IRBEWIN.

Taking other medicines with CO-IRBEWIN:

Always tell your healthcare professional if you are taking any other medicine.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of CO-IRBEWIN with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Diuretic agents such as the one contained in CO-IRBEWIN may interact with other medicines. Preparations containing lithium should not be taken with CO-IRBEWIN. Special precautionary

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measures (e.g. blood tests) may be appropriate if you take potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines, medicines for the treatment of gout, or if you take medicines to control heart rhythm or for diabetes (oral agents or insulins).
It is important to tell you doctor if you are taking medicines containing aliskiren or called Angiotensin Converting Enzyme Inhibitors (ACEIs), used to reduce your blood pressure; or pain and anti-inflammatory medicines called Non-Steroidal Anti-Inflammatory Medicines (NSAIMs).
Fluoroquinolones (used to treat bacterial infections, such as levofloxacin, ciprofloxacin or moxifloxacin) may also cause an interaction when used in combination with CO-IRBEWIN (see DO NOT TAKE CO-IRBEWIN).

You may need to have blood checks if you take:

- carbamazepine (a medicine used to treat epilepsy).

HOW TO TAKE CO-IRBEWIN

Always take CO-IRBEWIN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

CO-IRBEWIN will usually be prescribed by your doctor when your previous treatment for high blood pressure did not provide appropriate blood pressure reduction. Your doctor will instruct you how to switch from the previous treatment to CO-IRBEWIN.
The usual dose of CO-IRBEWIN is one tablet per day. The maximal blood pressure lowering effect should be reached 6–8 weeks after beginning treatment. Should your blood pressure not be appropriately reduced with CO-IRBEWIN, your doctor may prescribe the addition of another medicine.

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

CO-IRBEWIN can be taken with or without food. The tablets should be swallowed with a drink of water. You should try to take your daily dose at about the same time each day. It is important that you continue to take CO-IRBEWIN until your doctor tells you otherwise.

Do not share CO-IRBEWIN prescribed for you with any other person.

If you take more CO-IRBEWIN than you should:

If you accidentally take too many tablets, or a child swallows some, consult your doctor or pharmacist immediately. If neither is available, seek help at the nearest hospital or poison control centre without delay.

If you forget to take CO-IRBEWIN:

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

POSSIBLE SIDE EFFECTS

CO-IRBEWIN can have side effects.

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

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

- fainting
- yellowing of the skin and eyes, also called jaundice

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to CO-IRBEWIN. You may need urgent medical attention or hospitalization.

The following side effects may occur: headache, dizziness, fatigue, nausea, vomiting, an unexpected skin lesion or sensitivity to the sun or uv light during treatment which this may be an indication of skin or lip cancer, or abnormal urination. Other side effects that may be experienced are chest pain, cough, diarrhoea, dyspepsia, sexual dysfunction, thrombocytopenia (deficiency in blood platelets causing easy bruising and slow bloodclotting), a skin disease characterized by the peeling of the skin all over the body (psoriasis), increased sensitivity of the skin to the sun, and increased rate of heart beats.

One component of CO-IRBEWIN (hydrochlorothiazide) has been rarely associated with other more serious undesirable effects mainly affecting the blood, the skin or the kidneys.

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

STORING AND DISPOSAL INFORMATION

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

CO-IRBEWIN tablets should be stored in a dry place, at or below 25 °C. Do not leave them near a radiator, on a window sill or in a humid place.

Signed:

You will see an “Expiry date” on the carton and on the blister. Do not use the tablets after this date. Do not remove the tablets from the blister pack until you are ready to take the medicine.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION

CO-IRBEWIN tablets are supplied in blister packs of 28 or 30.

IDENTIFICATION OF CO-IRBEWIN

CO-IRBEWIN 150/12,5 tablets are peach (orange pink) coloured, biconvex, oval, film-coated tablets, engraved with a heart on one side and the number “2875” on the other side.
CO-IRBEWIN 300/12,5 tablets are peach (orange pink) coloured, biconvex, oval, film-coated tablets, engraved with a heart on one side and the number “2876” on the other side.

REGISTRATION NUMBERS

CO-IRBEWIN 150/12,5 tablets: A40/7.1.3/0290

CO-IRBEWIN 300/12,5 tablets: A40/7.1.3/0291

THE NAME AND THE BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE

Zentiva South Africa (Pty) Ltd

2 Bond Street

Midrand 1685

South Africa

Signed:

THE DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Registration date: 18 April 2008

Approved (revised) by the Authority: 31 July 2019

Signed: