

Approved Patient Information Leaflet for Medicines for Human Use:

ARBIN CO

SCHEDULING STATUS: S3

ARBIN CO 150/12,5 mg tablets

Each tablet contains 150 mg irbesartan and 12,5 mg hydrochlorothiazide

Contains sugar: 26 mg lactose monohydrate per tablet

ARBIN CO 300/12,5 mg tablets

Each tablet contains 300 mg irbesartan and 12,5 mg hydrochlorothiazide

Contains sugar: 52 mg lactose monohydrate per tablet

ARBIN CO 300/25 mg tablets

Each tablet contains 300 mg irbesartan and 25 mg hydrochlorothiazide

Contains sugar: 52 mg lactose monohydrate per tablet

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

- 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.
- ARBIN CO 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 ARBIN CO is and what it is used for
2. What you need to know before you take ARBIN CO
3. How to take ARBIN CO
4. Possible side effects

5. How to store ARBIN CO

6. Contents of the pack and other information

1. WHAT ARBIN CO IS AND WHAT IT IS USED FOR

ARBIN CO is a combination of two active substances, irbesartan and hydrochlorothiazide.

Irbesartan belongs to a group of medicines known as angiotensin-II receptor antagonists.

Angiotensin-II is a substance produced in the body that 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. Hydrochlorothiazide is one of a group of medicines (called thiazide diuretics) that causes increased urine output and so causes a lowering of blood pressure.

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

ARBIN CO is used to treat high blood pressure, when treatment with irbesartan or hydrochlorothiazide alone did not provide adequate control of your blood pressure.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ARBIN CO

Do not take ARBIN CO:

- if you are hypersensitive (allergic) to irbesartan or any other ingredients of ARBIN CO (listed in section 6).
- if you are hypersensitive (allergic) to hydrochlorothiazide or any other sulfonamide-derived medicines.
- 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 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 have kidney problems and are taking fluoroquinolones (a class of antibiotics)
- if you have porphyria
- if you have Addison's disease
- if you are treated with a blood pressure lowering medicine containing aliskirien.
- if you have previously had or currently have cancer of the skin and/or lip.

If you are not sure if any of these apply to you, talk to your doctor or pharmacist before taking ARBIN CO.

Warnings and precautions

Talk to your doctor or pharmacist before taking ARBIN CO:

- if you have heart, liver or kidney problems, or are on dialysis.
- if you have recently had a kidney transplant.
- if you are vomiting, have recently had severely vomiting, or have diarrhoea.
- if you have a disease of the adrenal gland called Conn's syndrome (also called primary hyperaldosteronism).
- if you have low blood pressure.
- if you have ever had a stroke.
- if you suffer from liver problems.
- if you suffer from diabetes.

- You must tell your doctor if you think you are (or might become) pregnant. ARBIN CO is not recommended in pregnancy.
- if you are taking any of the following medicines used to treat high blood pressure:
 - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
 - aliskiren
- if you are taking an ACE-inhibitor together with a medicine which belongs to the class of medicines known as mineralocorticoid receptors antagonists (MRA). These medicines are for the treatment of heart failure (see “Other medicines and ARBIN CO”).
- 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 ARBIN CO.

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

See also information under the heading “Do not take ARBIN CO”.

Your doctor may want to see you more often and do some tests if you have any of these conditions.

If you are going to have an operation, tell your doctor or dentist that you are taking ARBIN CO. This is because ARBIN CO, when combined with some anaesthetics, may cause an excessive drop in blood pressure.

You should also tell your doctor:

- If you are on a low-salt diet.

- If you have signs such as abnormal thirst, dry mouth, general weakness, drowsiness, muscle pain or cramps, nausea, vomiting, or an abnormally fast heartbeat which may indicate an excessive effect of hydrochlorothiazide (contained in ARBIN CO).
- 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 changes in your vision or pain in one or both of your eyes while taking ARBIN CO. This could be a sign that you are developing glaucoma, increased pressure in your eye(s). You should discontinue ARBIN CO treatment and seek medical attention.
- The hydrochlorothiazide contained in this medicine could produce a positive result in an anti-doping test.

Children and adolescents

ARBIN CO must not be given to children.

Other medicines and ARBIN CO

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

Tell your doctor if you are using any of the following medicines:

- Other medicines to help lower your blood pressure, including beta-blockers, diazoxide and ACE-inhibitors such as enalapril, captopril, lisinopril or ramipril.
- Non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, naproxen, diclofenac, celecoxib or etoricoxib (medicines to relieve pain and inflammation).
- Acetylsalicylic acid (if you are taking more than 3 g each day) (medicine to relieve pain and inflammation).
- Potassium supplements or salt substitutes containing potassium (medicines that increase the amount of potassium in your blood).
- Heparin (a medicine for thinning the blood).

- Co-trimoxazole (an antibiotic medicine) also known as trimethoprim/sulfamethoxazole
- Water tablets (diuretics)
- Medicines for diabetes
- Medicines for the treatment of gout
- Calcium salts and Vitamin D supplements
- Carbamazepine
- Colestyramine and colestipol resins
- Anticholinergic medicines
- Cytotoxic medicines
- Nondepolarizing skeletal muscle relaxants
- Medicines to control heart rhythm
- Lithium (a medicine for mental health problems).
- If you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take ARBIN CO” and “Warnings and precautions”).
- If you are being treated with an ACE-inhibitor together with certain other medicines to treat your heart failure, which are known as mineralocorticoid receptor antagonists (MRA) (for example: spironolactone, eplerenone).

Do not take ARBIN CO with fluoroquinolones (used to treat bacterial infections), such as levofloxacin, ciprofloxacin or moxifloxacin (see “DO NOT TAKE ARBIN CO”).

Diuretic medicines such as the hydrochlorothiazide contained in ARBIN CO may have an effect on other medicines.

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

ARBIN CO with food, drink

You can take ARBIN CO with or without food.

Pregnancy and breastfeeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will advise you to stop taking ARBIN CO before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of ARBIN CO. ARBIN CO is not recommended during pregnancy.

Breastfeeding

Tell your doctor if you are breastfeeding or about to start breastfeeding. ARBIN CO is not recommended for mothers who are breastfeeding, and your doctor may choose another treatment for you if you wish to breastfeed.

Driving and using machines

Some people may feel tired or dizzy when taking ARBIN CO. If this happens to you, do not drive or use any tools or machines.

It is not always possible to predict to what extent ARBIN CO may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which ARBIN CO affects them.

ARBIN CO 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.

3. HOW TO TAKE ARBIN CO

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

Always take this medicine exactly as your doctor or pharmacist has told you. Your doctor will tell you how long your treatment with ARBIN CO will last. Do not stop early treatment. If you have the impression that the effect of ARBIN CO is too strong or too weak, tell your doctor or pharmacist. You should check with your doctor or pharmacist if you are not sure.

Dosage

The usual dose is one tablet once a day.

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

Use in children and adolescents

ARBIN CO should not be given to children.

If you take more ARBIN CO than you should

If you accidentally take too many tablets, you may suffer from nausea, feeling drowsy, muscle spasms, change in heartbeat, dehydration, or low blood pressure.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ARBIN CO

Do not take a double dose to make up for a forgotten tablet.

If you stop taking ARBIN CO

If you stop taking ARBIN CO, your blood pressure may increase again. Therefore, do not stop taking ARBIN CO without first talking to your doctor.

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

4. POSSIBLE SIDE EFFECTS

ARBIN CO can have side effects.

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

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

- Difficulties in breathing, with or without swelling of the face, lips, tongue and/or throat.
- Swelling of the face, lips, tongue and/or throat, which may cause difficulties in swallowing.
- Severe itching of the skin (with raised lumps).

These are very serious side effects. If you have them, you may have had a serious reaction to ARBIN CO. 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:

- Tiredness, an infection or fever.
- Difficulty breathing.
- Yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems.

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:

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

If any of these side effects causes you problems, talk to your doctor.

Less frequent side effects:

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

If any of these side effects causes you problems, talk to your doctor.

Side effects associated with irbesartan alone

Frequent side effects:

- chest pain

Unknown frequency side effects:

- severe allergic reactions (anaphylactic shock), and decrease in the number of platelets (a blood cell essential for the clotting of the blood)

Side effects associated with hydrochlorothiazide alone

Unknown frequency side effects:

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, which can result in frequent infections, fever; decrease in the number of platelets (a blood cell essential for the clotting of the blood), decreased number of red blood cells (anaemia) characterised by tiredness, headaches, being short of breath when exercising, 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, which is identified by a rash that may appear on the face, neck, and scalp; 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.

Skin and lip cancer (non-melanoma skin cancer).

Reporting of side effects

If you get side effects, talk to your doctor or 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: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of ARBIN CO.

5. HOW TO STORE ARBIN CO

Store all medicines out of reach of children.

Store at or below 25 °C.

Store ARBIN CO in its original packaging to protect it from moisture.

Do not use this medicine after the expiry date which is stated on the carton, blister and bottle label after EXP. The expiry date refers to the last day of that month.

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 ARBIN CO contains

The active substances are irbesartan and hydrochlorothiazide.

The other ingredients for the tablet core are croscarmellose sodium, magnesium stearate, microcrystalline cellulose, poloxamer 188, pregelatinized starch. Please see section 2 “ARBIN CO contains lactose”.

ARBIN CO 150 /12,5 mg:

Each film-coated tablet contains 150 mg irbesartan and 12,5 mg hydrochlorothiazide.

ARBIN CO 300 /12,5 mg:

Each film-coated tablet contains 300 mg irbesartan and 12,5 mg hydrochlorothiazide.

ARBIN CO 300 /25 mg:

Each film-coated tablet contains 300 mg irbesartan and 25 mg hydrochlorothiazide.

The ingredients for the film-coating for ARBIN CO 150 / 12,5 mg and ARBIN CO 300 / 12,5 mg are Opadry pink 03A34089 consisting of Hypromellose 6cP, Iron Oxide yellow, Iron Oxide red, Microcrystalline cellulose, Purified stearic acid, Titanium dioxide.

The ingredients for the film-coating for ARBIN CO 300 / 25 mg are Opadry pink 03A36005 consisting of Hypromellose 6cP, Iron Oxide red, Iron Oxide black, Microcrystalline cellulose, Purified stearic acid, Titanium dioxide.

What ARBIN CO looks like and contents of the pack

ARBIN CO are packed in White PVC /PCTFE /Aluminium blisters packed into cardboard cartons in pack sizes of 30's.

ARBIN CO are packed in White PVC /PE /PVDC / Aluminium blisters packed into cardboard cartons in pack sizes of 30's.

ARBIN CO 150 /12,5 mg:

Light pink, oblong, biconvex film-coated tablets containing 150 /12,5 mg of
Irbesartan/Hydrochlorothiazide

ARBIN CO 300 /12,5 mg:

Light pink, oblong, biconvex film-coated tablets containing 300 /12,5 mg of
Irbesartan/Hydrochlorothiazide

ARBIN CO 300 / 25 mg:

Red-brick, oblong, biconvex, film-coated tablets with a scoreline containing 300 /25 mg of
Irbesartan/Hydrochlorothiazide

Not all pack sizes may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

Austell Pharmaceuticals (Pty) Ltd

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Parktown

JOHANNESBURG

2193

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ARBIN CO 300/12,5 mg: 46/7.1.3/0659

ARBIN CO 300/25 mg: 46/7.1.3/0660

Access to the corresponding Professional Information

Professional Information for this medicine is available on the following URL:

<https://austell.co.za/product-info/>

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