PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

ARBILO CO 50/12,5 film-coated tablets

ARBILO CO 100/25 film-coated tablets

Losartan and hydrochlorothiazide

Contains sugar.

Each ARBILO CO 50/12,5 film-coated tablet contains 25 mg lactose monohydrate

Each ARBILO CO 100/25 film-coated tablet contains 50 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking ARBILO CO

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- ARBILO 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 ARBILO CO is and what it is used for

ARBILO CO contains the active ingredients losartan and hydrochlorothiazide.

ARBILO CO is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide). 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. Losartan prevents the binding of angiotensin II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Hydrochlorothiazide works by making the kidneys pass more water and salt. This also helps to reduce blood pressure.

ARBILO CO is used to treat high blood pressure in patients established on identical doses of individual components of this medicine.

2. What you need to know before you take ARBILO CO

Do not take ARBILO CO

- If you are hypersensitive (allergic) to losartan, sulphonamide derived medicines or any of the other ingredients of ARBILO CO 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 renal artery stenosis (kidney problems with reduced blood supply to your 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 or amiloride).
- If you have porphyria (a disorder resulting from a build-up of natural chemicals that produce porphyrin in your body).
- If you have Addison’s disease (a disorder in which the adrenal glands, which sit on top of the

kidneys, do not produce enough of the hormones cortisol and aldosterone).

- If you are taking lithium.
- If you are pregnant or breastfeeding.
- If you have liver problems.
- If you have low levels of potassium in your blood (muscle weakness or cramps, abnormal heart rhythm).
- If you have high levels of calcium in your blood (stomach pain or constipation).
- If you have low levels of sodium in your blood (muscle cramps or weakness, loss of energy).
- If you have too much uric acid in your blood (severe pain, redness and swelling of the joints (gout)).
- If your kidneys stop producing urine (anuria).
- If you are being treated with a blood pressure lowering medicine containing aliskiren.
- If you have kidney impairment or are over the age of 65 and are using fluoroquinolones (used to treat bacterial infections).
- if you have previously had or currently have cancer of the skin and/or lip.

Warnings and precautions

Tell your doctor or health care provider before taking ARBILO CO:

- If you get excessive vomiting or diarrhoea (leading to salt/volume depletion).
- If you are on a salt-restricted diet.
- If you take diuretics (water pills) or potassium supplements.
- If you suffer from kidney problems.
- If you suffer from liver problems.
- If you suffer from heart problems.
- If you are taking medicines to lower blood pressure (such as an ACE inhibitor or aliskiren).
- If you have diabetes.
- If you have high cholesterol levels.
- If you suffer from gout.
- If you suffer from lupus erythematosus.

- If you are 65 years or older.
- If you have previously had skin cancer.

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

Tell your doctor that you are taking ARBILO CO if you have to have your parathyroid function tested.

Talk to your doctor immediately:

- If you develop sensitivity to the sun or UV light.
- 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 ultraviolet rays while taking ARBILO CO.

If you are going to have an operation (surgery) or be given anaesthetics (such as at the dentist's office), you should ensure that your doctor knows that you are taking ARBILO CO.

Children and adolescents

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

Other medicines and ARBILO CO

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

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).

- Non-steroidal anti-inflammatory drugs (NSAIDs) (used to treat pain, fever and inflammation).
- Medicines to control heart rhythm.
- Antipsychotic medicines (used to treat psychosis).
- Mizolastine (used to treat allergies).
- Halofantrine (used to treat malaria).
- Calcium supplements.
- Carbamazepine (used to treat seizures (fits)).

It is important to tell you doctor if you take:

- Other medicines to lower your blood pressure or medicines that may affect your blood pressure.
- Diuretics (water tablets).
- Fluoroquinolones (used to treat bacterial infections), such as levofloxacin, ciprofloxacin or moxifloxacin.
- Sleeping tablets or antidepressants.
- Medicines to treat diabetes, including insulin (high blood sugar levels).
- Cortisone-like medicines (used to treat inflamed areas of your body).
- Medicines to treat gout.
- Medicines used to treat cancer or arthritis.
- Ciclosporin (used to prevent organ rejection after a transplant).
- Laxative medicines.

ARBILO CO with food, drink and alcohol

Drinking alcohol while taking ARBILO CO may increase each other’s effects.

Pregnancy and breastfeeding

ARBILO CO is contraindicated in pregnancy and breastfeeding (see **Do not take ARBILO CO**).

If you are taking ARBILO CO, 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 ARBILO CO.

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

Driving and using machines

Your ability to drive and 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 ARBILO CO affects you.

ARBILO CO contains sugar (lactose monohydrate)

ARBILO CO contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take ARBILO CO

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

Always take ARBILO CO 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 one tablet of ARBILO CO per day.

Your doctor may prescribe you ARBILO CO with other medicines.

ARBILO CO can be taken with or without food.

Your doctor will tell you how long your treatment with ARBILO CO will last.

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

If you take more ARBILO CO than you should

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 ARBILO CO

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

ARBILO CO can have side effects.

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

If any of the following happens, stop taking ARBILO CO 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 ARBILO 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:

- pain in the chest, back, jaw and other areas of your upper body that lasts more than a few minutes or that goes away and comes back, shortness of breath,

- sudden numbness or weakness in the face, arm or leg, especially on one side of your body,
- decreased kidney function or kidney failure (causing drowsiness, shortness of breath, fatigue, confusion, nausea, fits, passing less urine than is normal for you),
- yellowing of the eyes or skin, also called jaundice or hepatitis,
- abnormal liver function (stomach pain, dark urine, unusual tiredness),
- too high levels of potassium in your blood (causing abnormal or slow heart rate, low blood pressure, cramps, weakness),
- painful, blistering or peeling skin rash, such as toxic epidermal necrolysis,
- bleeding or bruising more easily than normal,
- changes in the way your heart beats or chest pain,
- pancreatitis (nausea, vomiting, fever, pain in your stomach area radiating to your back),
- vasculitis (fever, headache, fatigue, weight loss, general aches and pains, night sweats, nerve problems such as numbness or weakness),
- red or purple pin-sized spots or bruising on the skin,
- haemolysis (causing pale skin, fever, weakness, dizziness, confusion),
- frequent infections such as fever, severe chills, sore throat or mouth ulcers,
- difficulty breathing, wheezing, shortness of breath.

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:

- changes in blood sugar levels,
- upper respiratory tract infection (sneezing, cough, runny nose, scratchy or sore throat, fever), sore throat or cough,
- headache or dizziness,
- feeling tired, abnormal physical weakness or lack of energy,
- sleeplessness,
- muscle cramps, pain in a muscle or group of muscles, back or leg pain,

- congestion in the nose, inflammation of the sinuses,
- diarrhoea or nausea (being sick).

Less frequent side effects:

- anaemia (fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration),
- gastritis (pain, nausea, vomiting, vomiting blood, blood in the stool),
- abnormal electrolyte levels (blood pressure changes, nausea, dizziness, unusual weakness, diarrhoea or constipation),
- dizziness or light-headedness when getting up from a lying or sitting position,
- increases in blood levels of urea and creatinine (substances that measures kidney function),
- red, itchy, burning eyes with a white or green discharge or thick yellow discharge,
- frequent urination including at night or urinary tract infection,
- low blood pressure,
- abnormal liver function tests,
- constant abnormal or foul taste in your mouth, discomfort or pain when opening your mouth or eating,
- runny nose or nose bleeds,
- difficulty in breathing, bronchitis, hoarseness,
- hair loss, dry skin, flushing or sweating,
- tinnitus (ringing in the ears) or vertigo (sensation of spinning or swaying),
- pain in the stomach area, stomach cramps or indigestion,
- gout,
- feeling anxious, nervous, confused, depressed, memory impairment or having panic attacks,
- tingling or numbness of your hands and feet (pins and needles), dropping things from your hands regularly, feeling of weakness or heaviness in your arms and legs, sharp stabbing pains,
- involuntary trembling or shaking of hands and feet,
- changes in sexual function or libido,
- blurred vision, visual impairment or burning of the eyes or seeing in yellow,

- abnormal dreams, feeling sleepy or having difficulty sleeping,
- loss of appetite,
- arm, knee or shoulder pain,
- muscle pain, stiffness or weakness,
- pain or swelling in a joint,
- constipation, nausea (feeling sick) or flatulence,
- toothache or dry mouth,
- fever.

The following side effects have been reported with unknown frequency:

- lip or skin cancer,
- cutaneous lupus erythematosus (autoimmune disease affecting the skin).
- temporary paralysis or weakness of muscles,
- sensitivity to the sun,
- distortion of the sense of taste.

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. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of ARBILO CO.

5. How to store ARBILO CO

- Store at or below 25 °C.
- Keep the blister strips 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 and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ARBILO CO contains

The active substances in ARBILO CO are losartan and hydrochlorothiazide.

ARBILO CO 50/12,5: Each tablet contains 50 mg losartan (as potassium) and 12,5 mg hydrochlorothiazide.

ARBILO CO 100/25: Each tablet contains 100 mg losartan (as potassium) and 25 mg hydrochlorothiazide.

The other ingredients in ARBILO CO are lactose monohydrate, magnesium stearate (E572), microcrystalline cellulose (E460), Opadry yellow (containing hydroxypropyl cellulose (E463), hypromellose (E464), quinoline yellow (E104) and titanium dioxide (E171)) and pregelatinised starch.

What ARBILO CO looks like and contents of the pack

ARBILO CO 50/12,5: Yellow coloured, oval shaped, film-coated tablets, debossed with ‘J’ on one side and ‘50+’ on the other.

ARBILO CO 100/25: Yellow coloured, oval shaped, film-coated tablets, debossed with ‘J’ on one side and ‘100+’ on the other.

ARBILO CO is packed in silver/grey aluminium/aluminium blister strips and placed in an outer carton.

Pack size: 30 tablets.

Holder of certificate of registration

Jubilant Pharma SA (Pty) Ltd

24 Parrot Avenue

Extension 1, Lenasia

Johannesburg

1820

Contact Details: g-rp.sa@jubl.com

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