MODULE 1.3.2 – Patient Information Leaflet

Product proprietary name:	***Losaar Plus 50/12,5 & Losaar Plus 100/25***
Dosage form and strength:	***50/12,5 mg & 100/25 mg Losartan-Hydrochlorothiazide per Tablet***
Applicant/PHCR:	***Accord Healthcare (Pty) Ltd***

SCHEDULING STATUS: S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

LOSAAR PLUS 100 /25 (tablets)

LOSAAR PLUS 50 /12,5 (tablets)

Read all of this leaflet carefully before you start taking LOSAAR PLUS:

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

LOSAAR PLUS 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.

1. WHAT LOSAAR PLUS CONTAINS:

Losaar Plus is a combination of an angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide).

Each tablet contains the following ingredients:

- **Losaar Plus 50/12,5 mg:**

  Each tablet contains: 50 mg losartan potassium and 12,5 mg hydrochlorothiazide

- **Losaar Plus 100/25 mg:**

  Each tablet contains: 100 mg losartan potassium and 25 mg hydrochlorothiazide

Inactive ingredients:

- hypromellose

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- lactose monohydrate
- magnesium stearate hydroxypropylcellulose
- microcrystalline cellulose
- pregelatinised maize starch
- talc
- titanium dioxide
- yellow iron oxide

2. WHAT LOSAAR PLUS IS USED FOR:

LOSAAR PLUS is a combination product which your doctor has prescribed because you have a condition known as hypertension or high blood pressure.

3. BEFORE YOU TAKE LOSAAR PLUS:

Do not take LOSAAR PLUS:

- if you are allergic (hypersensitive) to losartan, hydrochlorothiazide or to any of the other ingredients in this medicine
- if you are allergic (hypersensitive) to other sulfonamide-derived substances (e. g. other thiazides, some antibacterial medicines such as co-trimoxazole, ask your doctor if you are not sure)
- if you have a history of angioedema (that is swelling related to previous therapy)
- Hereditary or unknown causes of swelling of the face, lips, tongue and throat (angioedema)
- If you have hypertrophic obstructive cardiomyopathy (HOCM)
- If you have impaired liver function
- If you have impaired kidney function or if your kidneys are not producing any urine
- If you have a condition that causes the narrowing of the aorta as it comes out if the heart

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(aortic stenosis)

- If you are aware that you have low potassium, low sodium or high calcium levels which cannot be corrected by treatment
- If you have an inherited disorder of blood pigment metabolism known as porphyria
- If you have Addison's disease (a rare endocrine disorder where the adrenal glands produce insufficient steroid hormones) do not take thiazide diuretics (medicines to increase your urine frequency) together with LOSAAR PLUS
- If you undergoing lithium therapy while taking LOSAAR PLUS. This may lead to toxic blood concentrations of lithium
- If you are pregnant or breast-feeding

Take special care with LOSAAR PLUS:

Should you become pregnant while receiving LOSAAR PLUS, the treatment should be stopped immediately and switched to a different class of medicine.

- If you have impaired liver function
- If you have impaired kidney function
- If you are taking medicines to increase your urine (diuretics), this may cause low blood pressure
- If you are diabetic
- If you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland).
- if you have or have had an allergic condition, asthma or a condition that causes joint pain, skin rashes and fever (systemic lupus erythematosus)

Taking LOSAAR PLUS with food and drink:

You are advised not to drink alcohol whilst taking these tablets: alcohol and LOSAAR PLUS tablets may increase each other's effects.

Dietary salt in excessive quantities may counteract the effect of LOSAAR PLUS tablets. LOSAAR PLUS tablets may be taken with or without food.

Pregnancy and Breast-feeding:

When pregnancy is detected, LOSAAR PLUS should be discontinued as soon as possible.

If you are pregnant or breast-feeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:

You should not perform tasks which may require special attention (for example, driving or operating dangerous machinery) until you know how you tolerate your medicine.

Important information about some of the ingredients of LOSAAR PLUS:

Since LOSAAR PLUS contains lactose, you are advised not to take these tablets if you have rare hereditary problems, or a history of galactose intolerance, Lapp lactose deficiency or glucose-galactose malabsorption.

Taking other medicines with LOSAAR PLUS:

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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines,

including medicines obtained without a prescription such as complementary and traditional medicines.

Diuretic agents such as the hydrochlorothiazide contained in LOSAAR PLUS may interact with other medicines.

Special precautionary measures (e.g. blood tests) may be appropriate if you take potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines, other diuretics ("water tablets"), some laxatives, medicines for the treatment of gout, medicines to control heart rhythm or for diabetes (oral agents or insulins).

It is also important for your doctor to know if you are taking other medicines to reduce your blood pressure.

• Steroids.

• Medicines to treat cancer.

• Medicines to relieve pain.

• Medicines for treatment of fungal infections.

• Arthritis medicines.

• Resins used for high cholesterol, such as colestyramine.

• Medicines which relax your muscles.

• Sleeping tablets.

• Opioid medicines such as morphine.

• Pressor amines such as adrenaline or other medicines from the same group.

Please also inform your doctor that you are taking LOSAAR PLUS if you will be undergoing a radiographic procedure and will be given iodine contrast media.

4. HOW TO TAKE LOSAAR PLUS:

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

Always take LOSAAR PLUS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual starting and maintenance dose of LOSAAR PLUS 50/12,5 is one tablet once daily. For patients who do not respond adequately to LOSAAR PLUS 50/12,5, the dosage may be changed to one tablet of LOSAAR PLUS 100/25 once daily or two tablets of LOSAAR PLUS 50/12,5 once daily. The maximum dose is one tablet of LOSAAR PLUS 100/25 once daily or two tablets of LOSAAR PLUS 50/12,5 once daily. The maximum antihypertensive effect is attained within three weeks after initiation of therapy.

LOSAAR PLUS may be administered with or without food.

Your doctor will tell you how long your treatment with LOSAAR PLUS will last. If you have the impression that the effect of LOSAAR PLUS is too strong or too weak, tell your doctor or pharmacist.

If you take more LOSAAR PLUS than you should:

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

In case of an overdose, contact your doctor immediately so that medical attention may be given promptly. Overdosage can cause a drop in blood pressure, palpitations, slow pulse, changes in blood composition, and dehydration.

If you forget to take LOSAAR PLUS:

Try to take LOSAAR PLUS daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule. In case of an overdose, contact your doctor immediately. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS:

LOSAAR PLUS can have side effects:

Not all side effects reported for LOSAAR PLUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If you experience the following, stop taking LOSAAR PLUS and tell your doctor immediately or go to the casualty department of your nearest hospital:

- A severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing). This is a serious but infrequent side effect. You may need urgent medical attention or hospitalisation.

The following side effects have been reported:

Frequent:

• Cough, upper airway infection, congestion in the nose, sinusitis, sinus disorder.

• Diarrhoea, abdominal pain, nausea, indigestion.

• Muscle pain or cramps, leg pain, back pain.

• Insomnia, headache, dizziness.

• Weakness, tiredness, chest pain.

• Increased potassium levels (which can cause an abnormal heart rhythm), decreased haemoglobin levels.

Less Frequent:

• Anaemia, red or brownish spots on the skin (sometimes especially on the feet, legs, arms and buttocks, with joint pain, swelling of the hands and feet and stomach pain), bruising, reduction in white blood cells, clotting problems and bruising.

• Loss of appetite, increased uric acid levels or gout, increased blood sugar levels, abnormal blood electrolyte levels.

• Anxiety, nervousness, panic disorder (recurring panic attacks), confusion, depression, abnormal dreams, sleep disorders, sleepiness, memory impairment.

• Pins and needles or similar sensations, pain in the extremities, trembling, migraine, fainting.

• Blurred vision, burning or stinging in the eyes, conjunctivitis, worsening eyesight, seeing things in yellow.

• Ringing, buzzing, roaring or clicking in the ears.

• Low blood pressure, which may be associated with changes in posture (feeling light-headed or weak when you stand up), angina (chest pain), abnormal heartbeat, cerebrovascular accident (TIA, “mini-stroke”), heart attack, palpitations.

• Inflammation of blood vessels, which is often associated with a skin rash or bruising.

• Sore throat, breathlessness, bronchitis, pneumonia, water on the lungs (which causes difficulty breathing), nosebleed, runny nose, congestion.

• Constipation, wind, stomach upsets, stomach spasms, vomiting, dry mouth, inflammation of a salivary gland, toothache.

• Jaundice (yellowing of the eyes and skin), inflammation of the pancreas.

• Hives, itching, inflammation of the skin, rash, redness of the skin, sensitivity to light, dry skin,

flushing, sweating, hair loss.

• Pain in the arms, shoulders, hips, knees or other joints, joint swelling, stiffness, muscle weakness.

• Frequent urination including at night, abnormal kidney function including inflammation of the kidneys, urinary infection, sugar in the urine.

• Decreased sexual appetite, impotence.

• Swelling of the face, fever.

• Hepatitis (inflammation of the liver), abnormal liver function tests.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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

6. STORING AND DISPOSING OF LOSAAR PLUS:

Store at or below 25 °C. Keep in outer carton until before use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

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

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF LOSAAR PLUS:

LOSAAR PLUS 50/12,5: 10 tablets per white PVC/PE/PVDC blister strip, supplied in a pack size of 30.

LOSAAR PLUS 100/25: 10 tablets per white PVC/PE/PVDC blister strip, supplied in a pack size of 30.

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Dosage form and strength:	***50/12,5 mg & 100/25 mg Losartan-Hydrochlorothiazide per Tablet***
Applicant/PHCR:	***Accord Healthcare (Pty) Ltd***

8. IDENTIFICATION OF LOSAAR PLUS:

LOSAAR PLUS 100/25 tablets are yellow, round, film-coated tablets, scored on one side.

LOSAAR PLUS 50/12,5 tablets are yellow, oblong, film-coated tablets, scored on one side.

9. REGISTRATION NUMBER/REFERENCE NUMBER:

LOSAAR PLUS 50/12,5: 42/7.1.3/0325

LOSAAR PLUS 100/25: 42/7.1.3/0326

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Accord Healthcare (Pty) Ltd

Tuscany Office Park

6 Coombe Place

Rivonia

Gauteng

South Africa

11. DATE OF PUBLICATION:

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