
Clean amended proposed patient information leaflet for LOSARTAN BIOTECH 50**PATIENT INFORMATION LEAFLET****SCHEDULING STATUS:** **S3****LOSARTAN BIOTECH 50 film-coated tablets****Losartan potassium****Contains sugar:****Each film-coated tablet contains 2,16 mg lactose monohydrate.****Read all of this leaflet carefully before you start taking LOSARTAN BIOTECH 50.**

- 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.
- LOSARTAN BIOTECH 50 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 LOSARTAN BIOTECH 50 is and what it is used for
2. What you need to know before you take LOSARTAN BIOTECH 50
3. How to take LOSARTAN BIOTECH 50
4. Possible side effects
5. How to store LOSARTAN BIOTECH 50
6. Contents of the pack and other information.

1. What LOSARTAN BIOTECH 50 is and what it is used for

LOSARTAN BIOTECH 50 is an angiotensin II receptor antagonist which lowers blood pressure.

LOSARTAN BIOTECH 50 is used:

- To treat a condition known as hypertension or high blood pressure; or
- To protect the kidneys in type 2 diabetic patients with protein in their urine (proteinuria).

2. What you need to know before you take LOSARTAN BIOTECH 50

Do not take LOSARTAN BIOTECH 50:

- If you are hypersensitive (allergic) to losartan potassium or any of the other ingredients of LOSARTAN BIOTECH 50 (listed in section 6).
- If you are pregnant or breastfeeding.
- If you have a history of angioedema (severe reaction causing swelling of the face, lips, mouth, tongue or throat with or without difficulty in swallowing or breathing) relating to previous therapy with an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin receptor blocker, such as LOSARTAN BIOTECH 50, or if you suffer from hereditary/idiopathic angioedema.
- If you have a heart disorder affecting your heart muscle, known as hypertrophic obstructive cardiomyopathy.
- If you have severe kidney disease.
- If you have liver disease.
- If you have a heart disorder affecting your heart valves, known as aortic stenosis.
- If you have narrowing of the blood vessels to both, or to a single kidney.
- If you are taking diuretics (medicines that increase the amount of water that you eliminate through your kidneys (water pills), such as spironolactone, triamterene and amiloride) that cause your body to retain potassium.
- If you have a condition called porphyria (a rare hereditary disease in which there is abnormal metabolism of the blood pigment haemoglobin).
- Simultaneous administration of LOSARTAN BIOTECH 50 with lithium may lead to toxic blood concentrations of lithium.
- If you are taking blood pressure-lowering medicine containing aliskiren.

The safety of LOSARTAN BIOTECH 50 has not been established in children.

Warnings and precautions

Should you become pregnant while taking LOSARTAN BIOTECH 50, consult your doctor immediately. Your doctor will prescribe a different class of antihypertensive medicine for you, which is safe to use during pregnancy.

Special care should be taken with LOSARTAN BIOTECH 50:

- You should tell your doctor or pharmacist about any medical problems you have or have had and about any allergies.
- If you have recently suffered from excessive vomiting or diarrhoea.
- If you are taking diuretics (water pills) or are under dietary salt restrictions leading to an extreme loss of fluid and salt in your body.
- If you have liver or kidney disease.
- If you suffer from porphyria.
- If you have received a kidney transplant.
- If you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone).
- If you suffer from coronary heart disease or if you have had a stroke.
- If you suffer from heart failure. Special caution is necessary when you are taking a beta-blocker (used to treat an abnormal heartbeat).

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

Children and adolescents

There is no experience with the use of LOSARTAN BIOTECH 50 in children. Therefore, LOSARTAN BIOTECH 50 should not be given to children.

Other medicines and LOSARTAN BIOTECH 50

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 taking:

- Potassium-sparing diuretics (water pills), such as amiloride, triamterene and spironolactone.
- Heparin, used to prevent blood clotting.
- Trimethoprim-containing medicines, used to treat bacterial infections.
- Medicines and supplements containing potassium.
- Salt substitutes containing potassium.
- ACE inhibitors (e.g. enalapril, lisinopril, ramipril) or aliskiren, used to treat high blood pressure.
- Other medicines used to lower your blood pressure as they may cause a further reduction in your blood pressure.
- Tricyclic antidepressants, used to treat depression.
- Antipsychotics, used to treat psychotic disorders.
- Baclofen, used to treat muscle spasms.
- Amifostine, used to reduce the undesired side effects of certain cancer medicines.
- Fluconazole, used to treat fungal infections.
- Rifampicin, used to treat tuberculosis (TB).
- Lithium, used to treat depression or other mood disorders.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), such as indometacin, including cyclooxygenase-2 (COX-2) inhibitors and acetylsalicylic acid (aspirin), used to treat pain and inflammation.

LOSARTAN BIOTECH 50 with food and drink

See section 3.

Pregnancy and breastfeeding

You should not take LOSARTAN BIOTECH 50 if you are pregnant, breastfeeding or planning to become pregnant as safety in pregnancy and breastfeeding has not been established (see Do not take LOSARTAN BIOTECH 50). You should use adequate contraception while taking LOSARTAN BIOTECH 50.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking LOSARTAN BIOTECH 50.

Driving and using machines

LOSARTAN BIOTECH 50 may make you feel dizzy or drowsy. You should not perform tasks which may require special attention (for example, driving a vehicle or operating dangerous machines) until you are aware of the measure to which LOSARTAN BIOTECH 50 affects you.

LOSARTAN BIOTECH 50 contains potassium, lactose monohydrate and sodium

Although LOSARTAN BIOTECH 50 contains a very small amount of potassium, it cannot replace potassium supplements. If your doctor has prescribed potassium supplements, continue to follow his advice.

LOSARTAN BIOTECH 50 contains lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking LOSARTAN BIOTECH 50.

LOSARTAN BIOTECH 50 contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say it is essentially sodium free.

3. How to take LOSARTAN BIOTECH 50

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

Always take LOSARTAN BIOTECH 50 exactly as your doctor or pharmacist has told you. Check

with your doctor or pharmacist if you are not sure.

The usual dose of LOSARTAN BIOTECH 50 for most patients is 1 film-coated tablet per day to control blood pressure over the 24-hour period.

LOSARTAN BIOTECH 50 can be taken with or without food.

For convenience and to help you remember, try to take LOSARTAN BIOTECH 50 at the same time each day.

Your doctor will tell you how long your treatment with LOSARTAN BIOTECH 50 will last. It is important to continue taking LOSARTAN BIOTECH 50 for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

If you have the impression that the effect of LOSARTAN BIOTECH 50 is too strong or too weak, tell your doctor or pharmacist.

If you take more LOSARTAN BIOTECH 50 than you should

Symptoms of overdose are low blood pressure, increased heartbeat or a possible decreased heartbeat.

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 LOSARTAN BIOTECH 50

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

4. Possible side effects

LOSARTAN BIOTECH 50 can have side effects.

Not all side effects reported for LOSARTAN BIOTECH 50 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOSARTAN

BIOTECH 50, please consult your health care provider for advice.

If any of the following happens stop taking LOSARTAN BIOTECH 50 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, tongue and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are very serious side effects. If you have them, you may have had a serious reaction to LOSARTAN BIOTECH 50. 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:

- Frequent infections, such as fever, severe chills, sore throat or mouth ulcers.
- Bleeding or bruising more easily than normal.
- Angina (a feeling of tightness in your chest or severe chest pain).
- Changes in the way your heart beats, such as a fast or irregular heartbeat (palpitations).
- Narrowing or blockage of blood vessels due to inflammation (vasculitis including Henoch-Schönlein purpura).
- Severe constipation (obstipation).
- Liver problems (fever, feeling sick (nausea), being sick (vomiting), yellowing of the eyes and skin (jaundice), dark urine, light coloured bowel movements, fatigue and itching of the skin).
- Widespread reddening of your skin due to a severe inflammatory skin disease (erythroderma).
It is often associated with skin peeling off in scales or layers.
- Breakdown of your muscles known as rhabdomyolysis (unexplained muscle pain with dark (tea-coloured) urine).
- Pancreatitis (pain in your stomach area radiating to your back with nausea or vomiting).
- Kidney problems (build-up of fluid in your body causing swelling in your legs, ankles or feet,

passing little or no urine, severe pain in your lower back).

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:

- Flu-like symptoms.
- Decrease in the haemoglobin (substance in red blood cells that makes it possible for blood to carry oxygen throughout the body) concentrations characterised by tiredness, dizziness, feeling cold, pale skin, trouble breathing, headache and weakness.
- High potassium levels in your blood characterised by abdominal pain, chest pain, a fast or irregular heartbeat, muscle weakness or numbness in the limbs, nausea, vomiting and diarrhoea (hyperkalaemia).
- Headache.
- Dizziness.
- Vertigo (spinning sensation, loss of balance).
- *Low sugar (glucose) levels in your blood (hypoglycaemia) (increased sweating, weakness, hunger, dizziness, trembling, headache, flushing or paleness, numbness, having a fast, pounding heartbeat).

Less frequent side effects:

- Anaemia (tiredness, headaches, being short of breath when exercising, dizziness and looking pale).
- Low sodium levels in your blood characterised by nausea, vomiting, headache, confusion, fatigue, drowsiness, restlessness or irritability, muscle weakness, spasms or cramps, seizures and coma (hyponatraemia).
- Trouble sleeping (insomnia).
- Sleepiness.

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- Sleep disorders.
 - Migraine (severe headache).
 - *Low blood pressure characterised by dizziness and light-headedness.
 - *Dizziness on standing up, especially when getting up from a sitting or lying position (orthostatic hypotension).
 - Dry cough.
 - Blocked nose.
 - Sore throat and discomfort when swallowing (pharyngitis).
 - Sinus disorder.
 - Diarrhoea.
 - Indigestion.
 - Nausea.
 - Pain of your stomach area.
 - Raised liver enzyme values when blood tests are done.
 - Hives (urticaria).
 - A rare skin condition characterised by lesions or lumps under the skin (atypical cutaneous lymphoid infiltrates).
 - Back pain, muscle cramps, leg pain, aching muscles, muscle tenderness or weakness, not caused by exercise (myalgia).
 - *Unusual tiredness or weakness.

** Reported frequently only in type 2 diabetic patients with high blood pressure and protein in their urine.*

Side effects which may occur, but the frequency is unknown:

- Feeling depressed.
- Altered perception or complete loss of taste.
- Tinnitus (buzzing, hissing, whistling, ringing or other persistent noise in your ears).
- Increased sensitivity of the skin to sun (photosensitivity).

- Joint pain (arthralgia).
- Erectile dysfunction/impotence (inability to get or maintain an erection).
- Generally feeling unwell (malaise).

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 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: <https://www.sahpra.org.za/Publications/Index/8>

By reporting side effects, you can help provide more information on the safety of LOSARTAN BIOTECH 50.

5. How to store LOSARTAN BIOTECH 50

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Keep the blister strips in the carton until required for use.
- 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 LOSARTAN BIOTECH 50 contains

The active substance is losartan potassium.

Each LOSARTAN BIOTECH 50 film-coated tablet contains 50 mg losartan potassium.

The other ingredients are: Colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, povidone, sodium starch glycolate, Opadry White (OY-L-28900) (containing hypromellose (E464), lactose monohydrate, macrogol 4000 (E1521) and titanium dioxide (E171)).

What LOSARTAN BIOTECH 50 looks like and contents of the pack

White, oval, film-coated tablets with one notch on each side.

LOSARTAN BIOTECH 50 film-coated tablets are available in PVC/PVDC aluminium blister strips and/or HDPE containers with PP screw cap, in a pack size of 30 film-coated tablets.

Holder of Certificate of Registration

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