PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

LOSARTAN COMP BIOTECH 50/12,5 film-coated tablets

LOSARTAN COMP BIOTECH 100/25 film-coated tablets

Losartan potassium and hydrochlorothiazide

Contains sugar:

LOSARTAN COMP BIOTECH 50/12,5: Each film-coated tablet contains 26,9 mg lactose monohydrate.

LOSARTAN COMP BIOTECH 100/25: Each film-coated tablet contains 53,8 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking LOSARTAN COMP BIOTECH.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- LOSARTAN COMP BIOTECH 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 COMP BIOTECH is and what it is used for
2. What you need to know before you take LOSARTAN COMP BIOTECH
3. How to take LOSARTAN COMP BIOTECH
4. Possible side effects
5. How to store LOSARTAN COMP BIOTECH

6. Contents of the pack and other information.

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

LOSARTAN COMP BIOTECH is a combination of losartan potassium (an angiotensin II receptor type AT_1 antagonist) and hydrochlorothiazide (a diuretic).

LOSARTAN COMP BIOTECH is used in the treatment of a condition called hypertension or high blood pressure in patients established on identical doses of the individual components of this medicine.

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

Do not take LOSARTAN COMP BIOTECH

- If you are hypersensitive (allergic) to losartan potassium, other sulphonamide-derived medicines, due to the hydrochlorothiazide component or to any of the other ingredients of LOSARTAN COMP BIOTECH (listed in section 6).
- If you have a family history, or you previously experienced a severe reaction causing swelling of the face, lips, mouth, tongue or throat (known as angioedema) while taking an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin receptor blocker, such as LOSARTAN COMP BIOTECH.
- If you have problems with your heart valves or heart muscle.
- If you have a serious liver or kidney disorder.
- If you suffer from renal artery stenosis (a narrowing or blockage of the artery supplying blood to the kidney).
- If you have low levels of potassium in your blood (characterised by muscle weakness or cramps and an abnormal heart rhythm).
- If you have high levels of calcium in your blood (characterised by stomach pain or constipation).

- If you have low levels of sodium in your blood (characterised by muscle cramps, weakness and loss of energy).
- If you have too much uric acid in your blood (characterised by severe pain, redness and swelling of the joints (gout)).
- If you are also taking diuretics (medicines that increase the amount of water that you eliminate through your kidneys (water pills), such as spironolactone, triamterene or amiloride). This may cause your body to retain potassium.
- If you have a condition called porphyria (a disorder resulting from a build-up of natural chemicals that produce porphyrin in your body).
- If you have a condition called Addison's disease (a disorder in which the adrenal glands do not produce enough of the hormones cortisol and aldosterone).
- If you are unable to pass or produce urine.
- If you are taking lithium medicines.
- If you have diabetes mellitus or impaired kidney function and you are taking blood pressure-lowering medicines containing aliskiren.
- If you are pregnant or breastfeeding.
- if you have previously had or currently have cancer of the skin and/or lip.

Do not use in children as safety and efficacy of LOSARTAN COMP BIOTECH have not been established.

Warnings and precautions

Take special care with LOSARTAN COMP BIOTECH:

- If you have a fluid or electrolyte imbalance due to excessive perspiration, vomiting or diarrhoea.
- If you are taking diuretics (water pills) or potassium supplements.
- If you are on a salt-restricted diet.

- If you have a kidney or liver disorder.
- If you have received a kidney transplant.
- If you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone from the adrenal gland).
- If you suffer from coronary heart disease or if you have had a stroke.
- If you suffer from heart failure.
- If you are taking medicine to lower blood pressure (such as ACE inhibitors, other angiotensin II receptor blockers or aliskiren).
- If you have diabetes (high blood sugar) or are taking medicine to treat diabetes.
- If you have high cholesterol levels (high levels of fat in your blood).
- If you suffer from gout.
- If you suffer from lupus erythematosus (a chronic autoimmune disease that can cause severe fatigue and joint pain).

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 LOSARTAN COMP BIOTECH if you have to have your parathyroid function tested.

Talk to your doctor immediately:

- If you experience a decrease in vision or any eye pain. These could be symptoms of fluid accumulation in your eye or an increase of pressure in your eye and can happen within hours to weeks of taking LOSARTAN COMP BIOTECH. This can lead to permanent vision loss, if not treated. If you earlier

have had a penicillin or sulphonamide allergy, you can be at higher risk of developing eye problems.

- 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 (nonmelanoma skin cancer). Protect your skin from sun exposure and UV rays while taking LOSARTAN COMP BIOTECH.

After taking the first dose of LOSARTAN COMP BIOTECH, you may feel dizzy or light-headed.

Children and adolescents

LOSARTAN COMP BIOTECH should not be used in children and adolescents as the safety and efficacy have not been established.

Other medicines and LOSARTAN COMP BIOTECH

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.
- Trimethoprim-containing medicines, used to treat bacterial infections.
- Salt substitutes containing potassium.
- Medicines and supplements containing potassium.
- Lithium and carbamazepine used for seizures.
- ACE inhibitors (such as enalapril, lisinopril, ramipril) or aliskiren, used to treat high blood pressure.
- Other medicines used to reduce blood pressure, as they may cause a further reduction in your blood

pressure.

- 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.
- Rifampicin, used to treat tuberculosis (TB).
- Fluconazole, used to treat fungal infections.
- Nonsteroidal anti-inflammatory medicines (such as ibuprofen, indomethacin or aspirin).
- Alcohol or barbiturates (such as phenobarbital, used for seizures).
- Narcotics (such as morphine and codeine), used to treat moderate to severe pain.
- Antidiabetic medicines (such as metformin) and insulin, used to treat high blood sugar.
- Cholestyramine and colestipol, used to reduce cholesterol levels.
- Corticosteroids, used to treat inflammation.
- Adrenocorticotropic hormone, used to stimulate the release of the hormone cortisol.
- Noradrenaline and other medicines used to stimulate the sympathetic nervous system.
- Muscle relaxants such as tubocurarine.
- Medicines used to treat gout (such as probenecid, sulfinpyrazone, allopurinol).
- Anticholinergic medicines (such as atropine, biperiden), used to treat a variety of conditions including chronic obstructive pulmonary disease, bladder conditions, gastrointestinal disorders and symptoms of Parkinson’s disease.
- Cytotoxic medicines (such as cyclophosphamide, methotrexate), used to treat cancer and to suppress your immune system.
- Salicylates (such as aspirin), used to treat pain, fever and inflammation.
- Ciclosporin, used to prevent organ rejection after receiving an organ transplant.

- Digoxin, used to treat heart failure and an abnormal heartbeat.
- Other medicines used to control heartbeat.
- Bepridil, used to treat chest pain and high blood pressure.
- Cisapride, used to treat heartburn.
- Diphemanil, used to treat stomach ulcers.
- Intravenous erythromycin, used to treat bacterial infections.
- Halofantrine, used to treat malaria.
- Mizolastine and terfenadine, used to treat allergies.
- Pentamidine, used to treat fungal pneumonia.
- Intravenous vincamine, used to treat dementia.
- Calcium supplements.
- Iodine contrast media, used for X-ray imaging examinations.
- Parenteral amphotericin B, used to treat fungal infections.
- Laxative medicines, used to treat constipation.
- Glycyrrhizin (found in liquorice).

LOSARTAN COMP BIOTECH with food and drink

You are advised not to drink alcohol whilst taking LOSARTAN COMP BIOTECH. Alcohol and LOSARTAN COMP BIOTECH may increase each other's effects.

LOSARTAN COMP BIOTECH may be taken with or without food. However, simultaneous use of LOSARTAN COMP BIOTECH and liquorice should be avoided.

Pregnancy and breastfeeding

Do not take LOSARTAN COMP BIOTECH if you are pregnant, planning to become pregnant or

breastfeeding.

You should use adequate contraception to prevent pregnancy while taking LOSARTAN COMP BIOTECH. If you become pregnant while taking LOSARTAN COMP BIOTECH, please consult your doctor immediately to change your medicine.

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 COMP BIOTECH.

Driving and using machines

LOSARTAN COMP BIOTECH may cause dizziness or drowsiness. Please take care before driving or using machinery until you know how LOSARTAN COMP BIOTECH tablets affect you.

LOSARTAN COMP BIOTECH contains lactose monohydrate

LOSARTAN COMP BIOTECH 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 COMP BIOTECH.

3. How to take LOSARTAN COMP BIOTECH

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

Always take LOSARTAN COMP BIOTECH at the same time every day, 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 COMP BIOTECH 50/12,5 is one (1) film-coated tablet per day to control blood pressure over the 24-hour period. The maximum dose is one (1) LOSARTAN COMP BIOTECH 100/25 film-coated tablet once daily.

Your doctor will tell you how long your treatment with LOSARTAN COMP BIOTECH will last.

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

If you take more LOSARTAN COMP BIOTECH than you should

An overdose can cause a drop in blood pressure and changes in the way your heart beats (such as beating slower or faster than normal).

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 COMP BIOTECH

Take the missed dose as soon as possible. However, if it is almost time for your next dose, continue to take the next tablet at the usual time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking LOSARTAN COMP BIOTECH

If you have any further questions on the use of LOSARTAN COMP BIOTECH, ask your doctor or pharmacist.

4. Possible side effects

LOSARTAN COMP BIOTECH may have side effects.

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

If any of the following happens, stop taking LOSARTAN COMP BIOTECH 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 all very serious side effects. If you have them, you may have had a serious reaction to LOSARTAN COMP BIOTECH. 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:

- Narrowing or blockage of your blood vessels due to inflammation (vasculitis including Henoch-Schönlein purpura (symptoms include weight loss, general aches and pain, night sweats, nerve problems such as numbness)).
- Frequent infections, such as fever, severe chills, sore throat or mouth ulcers.
- Bleeding or bruising more easily than normal.
- Angina pectoris (a feeling of tightness in your chest or severe chest pain).
- Changes in the way your heart beats, such as a fast, slow or irregular heartbeat (palpitations).
- Severe constipation (obstipation).
- Liver problems characterised by nausea, yellowing of the eyes and skin (jaundice), dark urine, light coloured bowel movements.
- Breakdown of your muscles known as rhabdomyolysis (unexplained muscle pain with dark (tea-coloured) urine).
- Kidney problems (build-up of fluid in your body causing swelling in your legs, ankles or feet, difficulty to urinate, lower back pain).

- Low sodium levels in your blood (hyponatraemia) characterised by confusion, seizures (fits) and coma.
- Low potassium levels in your blood characterised by muscle damage.
- Abnormal accumulation of fluid in your eye (choroidal effusion).
- Build-up of pressure in your eye (acute angle-closure glaucoma).
- Skin lesions, as there is a risk of non-melanoma skin cancer (NMSC) associated with exposure to increasing cumulative doses of hydrochlorothiazide.
- Abnormal high pH levels in your body resulting from too little of the chloride ion in your blood (hypochloraemic alkalosis), which can lead to shock.
- Peripheral neuropathy (numbness or weakness in the arms).
- Stroke (damage to part of the brain caused by an interruption in blood supply. Symptoms can include collapse, numbness or weakness of the arms or legs, visual disturbance, difficulty swallowing, slurred speech or loss of speech).
- Heart attack.
- Difficulty breathing, wheezing, shortness of breath.
- Toxic epidermal necrolysis (painful blistering or peeling skin rash).

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:

- Feeling dizzy, weak, tired.
- Trouble sleeping (insomnia).
- Headache.
- Cough, blocked nose, sinus problems.

- Sore throat and discomfort when swallowing.
- Stomach pain, diarrhoea, indigestion, nausea (feeling sick).
- Back pain, leg pain.
- Aching muscles, muscle tenderness or weakness.
- Muscle spasms.
- Low sugar (glucose) levels in your blood characterised by increased hunger, trembling, flushing or paleness, numbness.
- Pain in the region of your head or neck.

Less frequent side effects:

- Raised liver enzyme levels when blood tests are done.
- Anaemia characterised by being short of breath and looking pale.
- The breakdown of red blood cells in your body (pale skin and shortness of breath).
- Loss of appetite (anorexia).
- Gout, characterised by painful, swollen joints.
- Feeling anxious, confused, depressed, nervous, drowsy.
- Abnormal dreams, sleep disturbances.
- Memory impairment.
- Tingling or numbness of the hands or feet (paraesthesia).
- Involuntary trembling or shaking of your hands and feet.
- Migraine (severe headache with or without an aura).
- Blurred vision or changes in your eyesight (such as seeing in yellow), burning or stinging of your eye.
- Discharge with itching of your eyes and crusty eyelids (conjunctivitis).
- Sensation of spinning or swaying (vertigo).

- Ringing noise in your ears (tinnitus).
- 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).
- Inflammation of your vocal cords characterised by a hoarse voice, sore throat and cough.
- Bronchitis characterised by shortness of breath, chest discomfort and chills.
- Runny nose or nosebleeds.
- Taste disturbances or complete loss of taste.
- Constipation.
- Toothache, dry mouth.
- Excessive gas (flatulence).
- A stomach problem which may result in pain, feeling sick (nausea), vomiting blood and blood in the stool (gastritis).
- Vomiting (being sick).
- A rare skin condition characterised by lesions or lumps under the skin (atypical lymphoid infiltrates).
- Unusual hair loss or thinning.
- Dry skin.
- Fibromyalgia characterised by widespread pain.
- Sensitivity to the sun or sun beds.
- Sweating.
- Pain in the arm, shoulder or knee.
- Swollen, painful joints.
- Need to urinate frequently.
- Urinary tract infection characterised by a strong, persistent urge to urinate, burning sensation when

urinating, cloudy urine, blood in the urine.

- Changes in sexual function or libido.
- Fever.
- High creatinine levels in your blood characterised by swelling, passing small amounts of urine, and nausea.
- Pin-point bleeds under the skin (purpura).
- Inflammation of your pancreas (pancreatitis) characterised by pain in your stomach area radiating to your back with nausea.
- High sugar (glucose) levels in the blood characterised by passing large amounts of urine and excessive thirst.
- Spasms and irritation of your stomach.
- Infection of your salivary gland characterised by enlarged, sore salivary glands.
- The presence of sugar in your urine.
- Restlessness or irritability.

The following side effects have been reported with unknown frequency:

- Feeling unwell (malaise).
- Acute short-sightedness.
- Cutaneous lupus erythematosus, characterised by a butterfly-shaped rash on your face that covers your cheeks and bridge of the nose.

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 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 LOSARTAN COMP BIOTECH.

5. How to store LOSARTAN COMP BIOTECH

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Keep blister strips in outer carton until required for use.
- Return expired medicine or 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 COMP BIOTECH contains

The active substances are losartan potassium and hydrochlorothiazide.

Each LOSARTAN COMP BIOTECH 50/12,5 film-coated tablet contains 50 mg losartan potassium and 12,5 mg hydrochlorothiazide.

Each LOSARTAN COMP BIOTECH 100/25 film-coated tablet contains 100 mg losartan potassium and 25 mg hydrochlorothiazide.

The other ingredients are: Colloidal silicon dioxide, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised starch, Tabcoat (TC 520074) (containing hydroxypropylcellulose, hypromellose, titanium dioxide, yellow iron oxide non-irradiated), talc.

What LOSARTAN COMP BIOTECH looks like and contents of the pack

LOSARTAN COMP BIOTECH 50/12,5: Light yellow, round, biconvex, film-coated tablets. Diameter: 8,0 - 8,3 mm; thickness: 3,3 - 3,8 mm.

LOSARTAN COMP BIOTECH 100/25: Light yellow, round, biconvex, film-coated tablets. Diameter: 10,0 - 10,2 mm; thickness: 4,5 - 5,1 mm.

LOSARTAN COMP BIOTECH 50/12,5 and 100/25 film-coated tablets are packed into silver aluminium/ aluminium blisters or blisters comprising of white ACLAR 3000 film and silver aluminium foil.

Each blister strip contains 10 film-coated tablets.

3 blister strips (30 film-coated tablets) are packed into a cardboard carton together with a patient information leaflet.

Holder of Certificate of Registration

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This leaflet was last revised in

13 January 2026

Registration numbers

LOSARTAN COMP BIOTECH 50/12,5: 43/7.1.3/0863

LOSARTAN COMP BIOTECH 100/25: 43/7.1.3/0864

Date of registration

20 June 2013