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 healthcare 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 healthcare 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 indomethacin, 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 healthcare 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 (23,0 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 healthcare 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.
- 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.

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LOSARTAN BIOTECH 50

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS:
S3

LOSARTAN BIOTECH 50 filmbedekte tablette
Losartan kalium
Bevat suiker:
Elke filmbedekte tablet bevat 2,16 mg laktosemonohidraat.

Lees die hele pamflet versigtig deur voordat jy begin om LOSARTAN BIOTECH 50 te neem.
- Hou hierdie pamflet. Jy mag dit dalk weer moet lees.
- Indien jy verdere vrae het, vra asseblief vir jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- LOSARTAN BIOTECH 50 is vir jou persoonlik voorgeskryf en jy moenie jou medisyne met ander mense deel nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as joune.

Wat is in die pamflet
1. Wat LOSARTAN BIOTECH 50 is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy LOSARTAN BIOTECH 50 neem
3. Hoe om LOSARTAN BIOTECH 50 te neem
4. Moontlike newe-effekte
5. Hoe om LOSARTAN BIOTECH 50 te bewaar
6. Inhoud van die pakkie en ander inligting.

1. Wat LOSARTAN BIOTECH 50 is en waarvoor dit gebruik word
LOSARTAN BIOTECH 50 is 'n angiotensien II reseptorantagonis wat bloeddruk verlaag.
LOSARTAN BIOTECH 50 word gebruik:
- Om 'n toestand genaamd hipertensie of hoë bloeddruk te behandel; of
- Om die niere te beskerm in Tipe 2 diabetiese pasiënte met proteïene in hul urien (proteïenurie).

2. Wat jy moet weet voordat jy LOSARTAN BIOTECH 50 neem
Moet nie LOSARTAN BIOTECH 50 neem nie as:
- Jy hipersensitief (allergies) is vir losartan kalium of vir enige van die ander bestanddele in LOSARTAN BIOTECH 50 (gelys in afdeling 6).
- Indien jy swanger is of jou baba borsvoed.
- Indien jy 'n geskiedenis het an angioedeem (ernstige reaksie wat swelling van die gesig, lippe, mond, tong of keel kan veroorsaak met of sonder moeilike sluk en asemhaling) wat verband hou met vorige terapie met 'n angiotensienomskakelende ensiem (ACE) inhibeerder of 'n angiotensienreseptor blokker soos LOSARTAN BIOTECH 50, of as jy aan oorerflike/ idiopatiese angioedeem ly.
- Indien jy 'n harttoestand het wat jou hartspier affekteer genaamd hipertrofiese obstruktiewe kardiomiopatie.
- Indien jy ernstige niersiekte het.
- Indien jy lewersiekte het.
- Indien jy 'n harttoestand het wat jou hartkleppe affekteer, bekend as aortastenose.
- Indien jy vernouing van bloedvate na een of beide van jou niere het.
- Indien jy diuretika neem (medisyne wat die hoeveelheid water wat deur die niere uitgeskei word verhood (waterpille) soos spironolaktoon, triamterene en amiloried) wat veroorsaak dat jou liggam kalium terughou.
- Indien jy 'n toestand het genaamd porfirie ('n seldsame oorerflike siekte waar daar 'n abnormale metabolisme van die bloedpigment heaemoglobien is).
- Gelyktydige toediening van LOSARTAN BIOTECH 50 met litium mag lei tot giftige bloedkonsentrasies van litium.
- Indien jy bloeddrukverlagende medisyne neem wat aliskiren bevat.

Die veiligheid van LOSARTAN BIOTECH 50 is nog nie vasgestel in kinders nie.

Waarskuwings en voorsorgmaatreëls

Indien jy sou swanger raak terwyl jy LOSARTAN BIOTECH 50 neem, raadpleeg jou dokter onmiddellik. Jou dokter sal 'n ander klas antihipertensiewe medisyne vir jou voorskryf wat veilig is om te gebruik gedurende swangerskap.

Spesiale sorg moet geneem word met LOSARTAN BIOTECH 50:
- Jy moet jou dokter of apteker vertel oor enige mediese probleme wat jy het of gehad het aangaande enige allergieë.
- Indien jy onlangs oormatige braking of diarree gehad het.
- Indien jy diuretika (watertablette) neem of dieetbeperkings van sout het wat lei tot 'n uitermatige verlies van vloeistof en sout in jou liggaam.
- Indien jy lewer of niersiekte het.
- Indien jy aan porferie ly.
- Indien jy 'n nieroorplanting ontvang het.
- Indien jy aan primêre hiperaldosteronisme lei ('n sindroom wat geassosieer word met verhoogde vrystelling van die hormoon aldosteroon).
- Indien jy aan koronêre hartsiekte ly of as jy voorheen 'n beroerte gehad het.
- Indien jy aan hartversaking ly. Spesiale versigtigheid is nodig wanneer jy 'n beta-blokker neem (gebruik om 'n abnormale hartklop te behandel).

Jou dokter mag jou nierfunksie, bloeddruk en hoeveelheid elektroliete (soos kalium) in jou bloed toets op gereelde intervalle.

Kinders en adolessente
Daar is geen ervaring met die gebruik van LOSARTAN BIOTECH 50 in kinders nie. Daarom moet LOSARTAN BIOTECH 50 nie aan kinders gegee word nie.

Ander medisyne en LOSARTAN BIOTECH 50
Vertel altyd jou gesonheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre en tradisionele medisyne in).

Vertel jou dokter indien jy die volgende neem:
- Kaliumsparende diuretika (waterpille), soos amiloride, triamterene en spironolaktoon.
- Heparien, wat gebruik word om bloedklonting te voorkom.
- Trimetopriem-bevattende medisyne wat gebruik word om bakteriële infeksies te behandel.
- Medisyne en aanvullings wat kalium bevat.
- Sout plaasvervangers wat kalium bevat.
- ACE-inhibeerders (bv. enalapril, lisinopril, ramipril) of aliskiren, wat gebruik word om hoë bloeddruk te behandel.
- Ander medisyne wat gebruik word om jou bloeddruk te verlaag, aangesien hulle 'n verdere verlaging in jou bloeddruk mag veroor saak.
- Trisikliese antidepressante wat gebruik word om depressie te behandel.
- Antipsigotiese medisyne wat gebruik word om psigotiese versteurings te behandel.
- Baklofeen wat gebruik word om spierspasmas te behandel.
- Amifostien wat gebruik word om die ongewensde effekte van sekere kankermedisyne te verminder.
- Flukonasool wat gebruik word om swaminfeksies te behandel.
- Rifampisien wat gebruik word om tuberkulose (TB) te behandel.
- Litium wat gebruik word om depressiewe en ander gemoedsversteuring te behandel.
- Nie- steroïed antiinflammatoriese middels (NSAIDs), soos indometasien, insluitend siklooksigenase-2 (COX-2) inhibeerders en asetielsalisielsuur (aspirien), wat gebruik word om pyn en inflammasie te behandel.

LOSARTAN BIOTECH 50 met kos en drank
Sien afdeling 3.

Swangerskap en borsvoeding
Jy moenie LOSARTAN BIOTECH 50 neem indien jy swanger is, jou baba borsvoed of beplan om swanger te raak nie aangesien die veiligheid in swangerskap en borsvoeding nog nie vasgestel is nie (sien Moenie LOSARTAN BIOTECH 50 neem nie). Jy moet gepasde voorbehoeding gebruik terwyl jy LOSARTAN BIOTECH 50 neem.
Indien jy swanger is of jou baba borsvoed, dink dat jy dalk mag swanger wees of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy LOSARTAN BIOTECH 50 neem.

Bestuur en die gebruik van masjiene
LOSARTAN BIOTECH 50 mag jou duiselig of lomerig laat voel. Jy moet nie take verrig wat spesiale aandag benodig nie (bv die bestuur van 'n motor of die hantering van gevaarlike masjinerie) totdat jy bewus is van die mate waarin LOSARTAN BIOTECH 50 jou affekteer nie.

LOSARTAN BIOTECH 50 bevat kalium, laktosemonohidraat en natrium
Alhoewel LOSARTAN BIOTECH 50 'n baie klein hoeveelheid kalium bevat, kan dit nie kaliumaanvullings vervang nie. Indien jou dokter kaliumaanvullings voorgeskryf het, hou aan om sy/ haar advies te volg.
LOSARTAN BIOTECH 50 bevat laktosemonohidraat. Indien jy deur jou dokter vertel is dat jy onverdraagsaam is teenoor sekere suikers, kontak jou dokter voordat jy LOSARTAN BIOTECH 50 neem.
LOSARTAN BIOTECH 50 bevat minder as 1 mmol natrium (23 mg) per filmbedekte tablet en is dus so te sê natrium-vry.

3. Hoe om LOSARTAN BIOTECH 50 te neem
Moenie medisyne wat vir jou voorgeskryf is met enige ander person deel nie.
Neem altyd LOSARTAN BIOTECH 50 presies soos jou dokter of apteker vir jou vertel het. Indien jy nie seker is nie, raadpleeg jou dokter of apteker.
Die gewone dosis van LOSARTAN BIOTECH 50 vir die meeste pasiënte is 1 filmbedekte tablet per dag om jou bloeddruk oor die 24-uur periode te beheer.
LOSARTAN BIOTECH 50 kan met of sonder kos geneem word.
Vir gerief en om te help dat jy onthou, probeer om LOSARTAN BIOTECH 50 elke dag op dieselfde tyd te neem.
Jou dokter sal jou vertel hoe lank jou behandeling met LOSARTAN BIOTECH 50 sal aanhou. Dit is belangrik om aan te hou om LOSARTAN BIOTECH 50 te neem vir so lank as wat jou dokter dit voorskryf om goeie beheer van jou bloeddruk te behou.
Indien jy onder die indruk is dat die effek van LOSARTAN BIOTECH 50 te sterk of te swak is, vertel jou dokter of apteker.

Indien jy meer LOSARTAN BIOTECH 50 neem as wat jy moet
Simptome van 'n oordosis is lae bloeddruk, vinnige hartklop of 'n moontlike verlaagde hartklop.
In die geval van 'n oordosis, raadpleeg jou dokter of apteker. Indien hulle nie beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

Indien jy vergeet om LOSARTAN BIOTECH 50 te neem
Moenie 'n dubbeldosis neem om op te maak vir 'n vergete individuele dosisse nie.

4. Moontlike newe-effekte
LOSARTAN BIOTECH 50 kan newe-effekte hê.
Nie al die newe-effekte wat vir LOSARTAN BIOTECH 50 aangemeld is word in hierdie pamflet genoem nie. Sou jou algemene gesondheid verswak of as jy enige ongewensde effekte sou ervaar terwyl jy LOSARTAN BIOTECH 50 neem, raadpleeg asseblief jou gesondheid-sorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak dadelik die gebruik van LOSARTAN BIOTECH 50 en vertel jou dokter dadelik of gaan na die ongevalle-afdeling van jou naaste hospitaal:
- Swelling van jou hande, voete, enkels, gesig, lippe, tong en mond of keel wat veroorsaak dat jy moeilik sluk of asemhaal.
- Uitslag of jeuk.
- Floute.

Hierdie is almal baie ernstige newe-effekte. Indien jy dit het mag jy dalk 'n ernstige reaksie vir LOSARTAN BIOTECH 50 gehad het. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

Vertel dadelik jou dokter of gaan na die ongevalle-afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:
- Gereelde infeksies soos koors, erge kouekoors, seer keel of mondsere.
- Bloeding of kneusing wat makliker gebeur as normaalweg.
- Angina ('n stywe gevoel in jou bors of erge borspyn).
- Verandering in die manier hoe jou hart klop soos 'n vinnige en ongereelde kartklop (hartkloppings).
- Vernouing of blok van bloedvate as gevolg van inflammasie (Vaskulitis insluitende Henoch-Schönlein purpura).
- Erge hardlywigheid.
- Lewer probleme (koors, siek gevoel (naarheid), siek wees (braking), vergeling van die oë en vel (geelsug), donker uriene, liggekleurde stoelgange, moegheid en jeuk van die vel).
- Wydverspreide rooiheid van jou vel as gevolg van 'n ernstige inflammatoriese velsiekte (erithroderma). Dit word dikwels geassosieer met velafskilfering met skubbe of lae.
- Afbraak van jou spiere wat bekend staan as rabdomiolise (onverklaarbare spierptyn met donker (tee gekleurde) uriene).
- Pankreatitis (pyn in jou maagarea wat verwys na jou rug met naarheid of braking).
- Nierprobleme (opbou van vloeistof in jou liggaam wat swelling van jou bene, enkels of voete veroorsaak, uitskeiding van min tot geen uriene, erge pyn in jou lae rug).

Hierdie is almal ernstige newe-effekte. Jy mag dringende mediese aandag benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:
Gereelde newe-effekte:
- Griepagtige simptome.
- Verlaging in die haemoglobienkonsentrasies (stof in rooibloedselle wat dit moontlik maak vir die bloed om suurstof deur die liggaam te vervoer) wat gekenmerk word deur moegheid, duiseligheid, koue gevoel, bleek vel, moeilike asemhaling, hoofpyn en swakheid.
- Hoë kaliumvlakke in jou bloed wat gekenmerk word deur maagpyn, borspyn, 'n vinnige of onreelmatige hartklop, spierswakheid of gevoelloosheid in die ledemate, naarheid, braking en diarree (hiperkalemie).
- Hoofpyn.
- Duiseligheid.
- Vertigo (tollende sensasie, verlies van balaans).
- *Lae bloedglukose (suiker) vlakke in jou bloed (hipoglukemie) (verhoodge sweet, swakheid, honger, duiseligheid, bewing, hoofpyn, blosing of bleekheid, gevoelloosheid en 'n vinnige, stampende hartklop).

Minder gereelde newe-effekte:
- Bloedarmoede (moegheid, hoofpyne, kort van asem wees wanneer jy oefen, duiseligheid en bleek voorkoms).
- Lae natriumvlakke in jou bloed wat gekenmerk word deur naarheid, braking, hoofpyn, verwarring, moegheid, slaperigheid, rusteloosheid of prikkelbaarheid, spierswakheid, spasmas of krampe, aanvalle (stuiptrekkings) en koma.
- Moeilikheid met slaap (slapeloosheid).
- Slaperigheid.
- Slaapversteurings.
- Migraine (erge hoofpyne).
- *Lae bloeddruk gekenmerk aan duiseligheid en lighoofdigheid.
- *Duiseligheid wanneer jy opstaan, veral vanaf 'n sittende of lêende posisie(ortostatiese hipotensie).
- Droë hoes.
- Verstopte neus.
- Seer keel en ongemak wanneer jy sluk (pharyngitis).
- Sinusversteuring.
- Diarree.
- Slegte spysvertering.
- Naarheid.
- Pyn in jou maagarea.
- Verhoogde lewerensiemwaardes wanneer bloedtoetse gedoen word.
- Korwe (urticaria).
- 'n Skaars veltoestand wat gekenmerk word deur letsels of knoppe onder die vel (atipiese kutane limfoïed infiltrate).
- Rugpyn. Spierkrampe, beenpyn, seer spiere, spierteerheid of swakheid wat nie veroorsaak is deur oefening nie (myalgie).
- *Ongewone moegheid of swakheid.

** Gereeld gerapporteer slegs in tipe 2 diabetiese pasiënte met hoë bloeddruk en proteïen in hul uriene.*

Newe-effekte wat mag voorkom, maar die frekwensie is onbekend:
- Depressiewe gevoel.
- Veranderde persepsie of volle verlies van smaak.
- Tinnitus (gons, sis, fluit, lui of ander aanhoudende geluide in jou ore.
- Verhoogde sensitiwiteit van die vel vir die son (fotosensitiwiteit).
- Gewrigspyn (artralgie).
- Erektiele disfunksie/ impotensie (onvermoë om 'n ereksie te kry of te behou).
- Algemene gevoel van ongesteldheid (malaise).

Indien jy enige newe-effekte opmerk wat nie in hierdie pamflet genome word nie, stel asseblief jou dokter of apteker in kennis.

Rapportering van newe-effekte
Indien jy newe-effekte ervaar, raadpleeg jou dokter, apteker of verpleegster. Jy kan ook newe-effekte rapporteer aan SAHPRA deur die **6.04 Adverse Drug Reaction Reporting Form**, wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8
Deur newe-effekte te rapporteer kan jy help om meer inligting te voorsien oor die veiligheid van LOSARTAN BIOTECH 50.

5. Hoe om LOSARTAN BIOTECH 50 te bewaar
- Bewaar alle medisyne buite bereik van kinders.
- Bewaar teen of benede 25 °C.
- Hou die stulpstroke in die karton totdat dit benodig word vir gebruik.
- Gee alle ongebruikte medisyne terug aan jou apteker.
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pakkie en ander inligting
Wat LOSARTAN BIOTECH 50 bevat
Die aktiewe bestanddeel is losartan kalium.
Elke LOSARTAN BIOTECH 50 filmbedekte tablet bevat 50,0 mg losartan kalium.
Die ander bestanddele is: Kolloïdale silikondioksied, magnesiusteraat, mikrokristallyne sellulose, povidoon, natriumstyselglykolaat, Opadry Wit (OY-L-28900) (wat hipromellose (E464), laktosemonohidraat, makrogol 4000 (E1521) en titaandioksied (E171) bevat).

Hoe LOSARTAN BIOTECH 50 lyk en die inhoud van die pakkie
Wit, ovaal, filmbedekte tablette met een kerf aan elke kant.
LOSARTAN BIOTECH 50 filmbedekte tablette is beskikbaar in PVC/PVDC aluminium stulpstroke en/ of HDPE houers met 'n PP skroefdop in 'n pakgroote van 30 filmbedekte tablette.

Houer van die Sertifikaat van Registrasie
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Hierdie pamflet is laas hersien in
28 November 2022

Registrasienommer
A40/7.1.3/0069

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