AMLODIPINE/VALSARTAN BIOTECH

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

AMLODIPINE/VALSARTAN 5/160 BIOTECH film-coated tablets (5 mg amlodipine and 160 mg valsartan)
AMLODIPINE/VALSARTAN 10/160 BIOTECH film-coated tablets (10 mg amlodipine and 160 mg valsartan)
Amlodipine and valsartan
Sugar free.

Read all of this leaflet carefully before you start taking AMLODIPINE/ VALSARTAN BIOTECH.
- 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.
- AMLODIPINE/VALSARTAN 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 AMLODIPINE/VALSARTAN BIOTECH is and what it is used for.
2. What you need to know before you take AMLODIPINE/VALSARTAN BIOTECH.
3. How to take AMLODIPINE/VALSARTAN BIOTECH.
4. Possible side effects.
5. How to store AMLODIPINE/VALSARTAN BIOTECH.
6. Contents of the pack and other information.

1. What AMLODIPINE/VALSARTAN BIOTECH is and what it is used for
AMLODIPINE/VALSARTAN BIOTECH contains two substances called amlodipine and valsartan. Both of these substances help to control high blood pressure.

Amlodipine belongs to a group of substances called "calcium channel blockers". Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening.
Valsartan belongs to a group of substances called "angiotensin-II receptor antagonists". Angiotensin II is produced by the body and makes the blood vessels tighten, thus increasing the blood pressure. Valsartan works by blocking the effect of angiotensin II.

This means that both of these substances help to stop the blood vessels tightening. As a result, the blood vessels relax and blood pressure is lowered.
AMLODIPINE/VALSARTAN BIOTECH is used to treat high blood pressure in adults whose blood pressure is not controlled enough with either amlodipine or valsartan on its own.

2. What you need to know before you take AMLODIPINE/VALSARTAN BIOTECH
Do not take AMLODIPINE/VALSARTAN BIOTECH
- If you are hypersensitive (allergic) to amlodipine or any other calcium channel blockers, valsartan or to any of the other ingredients of AMLODIPINE/VALSARTAN BIOTECH (listed in section 6).
- If you have experienced swelling, particularly of the face and throat, while taking other medicines (including angiotensin converting enzyme inhibitors). If you get these symptoms, stop taking AMLODIPINE/ VALSARTAN BIOTECH and contact your doctor straight away. You should never take AMLODIPINE/VALSARTAN BIOTECH again.
- If you have recurrent episodes of severe swelling.
- If your doctor has diagnosed that you are suffering from a narrowing of valves in your heart (called aortic or mitral stenosis), or abnormally increased thickness of your heart muscle with narrowing (called obstructive hypertrophic cardiomyopathy).
- If you have received a kidney transplant or if you had been diagnosed to suffer from a narrowing of your kidney artery or if you are suffering from severe kidney problems.
- If you are taking other medicine or substances, which increase the potassium levels in your blood (such as certain types of diuretics, potassium supplements, etc.).
- If you have porphyria.
- If you are taking a medicine called lithium.
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- If you have severe liver impairment.
- If you have severe low blood pressure (hypotension).
- If you have cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- If you suffer from heart failure after a heart attack.
- If you are pregnant or breastfeeding.

Warnings and precautions
Take special care with AMLODIPINE/VALSARTAN BIOTECH:
- If you are taking aliskiren (see "Do not take").
- If you have been sick (vomiting or diarrhoea).
- If you have had a kidney transplant or if you had been told that you have a narrowing of your kidney arteries.
- If you have liver or kidney problems.
- If you have a condition affecting the renal glands called "primary hyperaldosteronism".
- If you have experienced swelling, particularly of the face and throat, while taking other medicines (including angiotensin converting enzyme inhibitors). If you get these symptoms, stop taking AMLODIPINE/ VALSARTAN BIOTECH and contact your doctor straight away. You should never take AMLODIPINE/VALSARTAN BIOTECH again.
- If you have had heart failure or have experienced a heart attack. Follow your doctor's instructions for the starting dose carefully. Your doctor may also check your kidney function.

Contact your doctor to re-evaluate your treatment if you are treated with ACE inhibitors/angiotensin receptor blockers together with a fluoroquinolone antibiotic.
Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

Children and adolescents
The use of AMLODIPINE/VALSARTAN BIOTECH in children and adolescents is not recommended (aged below 18 years old).

Other medicines and AMLODIPINE/VALSARTAN 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:
- ACE inhibitors or aliskiren (medicines used to treat high blood pressure) (see also information under the headings "Do not take AMLODIPINE/ VALSARTAN BIOTECH");
- diuretics (a type of medicine also called "water tablets" which increases the amount of urine you produce);
- potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium and other substances that may increase potassium levels;
- nitroglycerin and other nitrates, or other substances called "vasodilators";
- medicines used for HIV/AIDS (e.g. ritonavir, indinavir, nelfinavir);
- medicines used to treat fungal infections (e.g. ketoconazole, itraconazole);
- clarithromycin (for infections caused by bacteria);
- verapamil, diltiazem (heart medicines);
- medicines used to treat bacterial infections (such as rifampicin, erythromycin, talithromycin);
- anticonvulsant medicines (e.g. carbamazepine, phenobarbitone, phenytoin, fosphenytoin, primidone);
- St. John's wort;
- simvastatin (a medicine used to control high cholesterol levels);
- dantrolene (infusion for severe body temperature abnormalities);
- tacrolimus (used to control your body's immune response, enabling your body to accept the transplanted organ);
- medicines used to protect against transplant rejection (ciclosporin);
- lithium (a medicine used to treat some types of depression) (see also information under the headings "Do not take AMLODIPINE/VALSARTAN BIOTECH")
- certain types of painkillers called non-steroidal anti-inflammatory drugs (NSAIDs) or selective cyclooxygenase-2 inhibitors (COX-2 inhibitors). Your doctor may also check your kidney function.

AMLODIPINE/VALSARTAN BIOTECH with food and drink
Grapefruit and grapefruit juice should not be consumed by people who are taking AMLODIPINE/VALSARTAN BIOTECH. This is because grapefruit and grapefruit juice can lead to an increase in the blood levels of the active substance amlodipine, which can cause an unpredictable increase in the blood pressure lowering effect of AMLODIPINE/VALSARTAN BIOTECH.

Pregnancy and breastfeeding
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 AMLODIPINE/VALSARTAN BIOTECH.
Safety of AMLODIPINE/VALSARTAN BIOTECH in pregnant and breastfeeding women has not been established.
You should not use AMLODIPINE/VALSARTAN BIOTECH if you are pregnant, trying to become pregnant or breastfeeding your baby.
If you are a woman of childbearing age, you should ensure that you use an effective contraception.

Driving and using machines
This medicine may make you feel dizzy. This can affect how well you can concentrate.

It is not always possible to predict to what extent AMLODIPINE/VALSARTAN BIOTECH may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or operate machines until you are aware of the measure to which AMLODIPINE/VALSARTAN BIOTECH affects you.

3. How to take AMLODIPINE/VALSARTAN BIOTECH
Do not share medicines prescribed for you with any other person.
Always take AMLODIPINE/VALSARTAN BIOTECH exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of AMLODIPINE/VALSARTAN BIOTECH is one tablet per day.
- It is preferable to take your medicine at the same time each day.
- Swallow the tablets with a glass of water.
- You can take AMLODIPINE/VALSARTAN BIOTECH with or without food. Do not take AMLODIPINE/VALSARTAN BIOTECH with grapefruit or grapefruit juice.

Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

Do not exceed the prescribed dose.

AMLODIPINE/VALSARTAN BIOTECH and older people (age 65 years or over)
Your doctor should exercise caution when increasing your dose.

If you take more AMLODIPINE/VALSARTAN BIOTECH than you should
Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may only develop later (24 – 48 hours after intake). You may stop breathing and need to be ventilated.

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

If you forget to take AMLODIPINE/VALSARTAN BIOTECH
Do not take a double dose to make up for forgotten individual doses.

If you stop taking AMLODIPINE/VALSARTAN BIOTECH
Stopping your treatment with AMLODIPINE/VALSARTAN BIOTECH may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

4. Possible side effects
AMLODIPINE/VALSARTAN BIOTECH can have side effects.
Not all side effects reported for AMLODIPINE/VALSARTAN BIOTECH are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking AMLODIPINE/VALSARTAN BIOTECH, please consult your healthcare provider for advice.

If any of the following happens, stop taking AMLODIPINE/ VALSARTAN BIOTECH and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips, 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 allergic reaction to AMLODIPINE/VALSARTAN 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:
- sudden wheeziness, chest pain, shortness of breath or difficulty in breathing;
- severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of the mucous membranes (Stevens-Johnson Syndrome, toxic epidermal necrolysis) or other allergic reactions;
- inflamed pancreas, which may cause severe abdominal and back pain accompanied with feeling of being very unwell;
- heart attack, abnormal heartbeat;
- upper airway swelling.

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
- influenza (flu); blocked nose, sore throat and discomfort when swallowing;
- low potassium levels;
- headache;
- asthenia (weakness);
- dizziness;
- stomach pain;
- feeling sick (nausea),
- tiredness;
- facial swelling;
- redness and warm feeling of the face and/or neck;
- swelling in the body caused by excess fluid. It often affects the lower body, such as the legs, feet, and ankle but it can occur anywhere.

Less frequent side effects
- lack of appetite;
- high calcium, sugar, cholesterol or uric acid levels in the blood;
- low levels of sodium in the blood;
- feeling anxious;
- abnormal coordination;
- drowsiness, tingling or numbness of the hands or feet;
- vision disturbance and impairment;
- ringing in your ears, head spinning;
- fast heartbeat including palpitations;
- low blood pressure and light-headedness when standing up;
- cough, sneezing/runny nose caused by inflammation of the lining of the nose (rhinitis);
- throat pain;
- constipation, change of bowel habit;
- diarrhoea, dry mouth;
- nausea, vomiting, indigestion;
- excessive sweating;
- redness of the skin;
- skin rash all over your body;
- joint swelling;
- back pain; pain in joints, muscle spasm, muscle cramps;
- sensation of heaviness;
- passing more urine than normal or feeling more of an urge to pass urine;
- inability to get or maintain an erection;
- a low level of white blood cells in the blood;
- low blood platelet count;
- excess sugar in blood (hyperglycaemia);
- mood changes, depression, confusion;
- taste abnormalities, loss of pain sensation, abnormal sensation, typically tingling or pricking ('pins and needles'), high level of muscle tone;
- trembling, sleeplessness, partial or total loss of sensation in a part of your body;
- an inflammation of the blood vessels that causes changes in the blood vessel walls;
- swelling of the gums;
- abdominal bloating (gastritis), increased liver enzyme increase which may have an effect on some medical tests;
- abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice);
- hair loss;
- skin discolouration;
- skin sensitivity to light, purple spots under the skin, hives;
- discomfort or enlargement of the breasts in men;
- lack of energy;
- chest pain, feeling unwell;
- pain;
- weight increase or decrease.

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 **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.
By reporting side effects, you can help provide more information on the safety of AMLODIPINE/VALSARTAN BIOTECH.

5. How to store AMLODIPINE/VALSARTAN BIOTECH
- Store at or below 25 °C.
- Protect from moisture.
- Blisters: Keep the blister strips in the outer carton until required for use.
- HDPE bottles: Keep in the outer container until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the blister/label/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 AMLODIPINE/VALSARTAN BIOTECH contains
AMLODIPINE/VALSARTAN BIOTECH 5/160: Each film-coated tablet contains 6,9 mg amlodipine besilate (equivalent to 5 mg amlodipine) and 160 mg valsartan.
AMLODIPINE/VALSARTAN BIOTECH 10/160: Each film-coated tablet contains 13,9 mg amlodipine besilate (equivalent to 10 mg amlodipine) and 160 mg valsartan.
The other ingredients are colloidal silicon dioxide (E551), crospovidone (E1201), magnesium stearate (E572), microcrystalline cellulose (E460(i)), Opadry Yellow (containing hypromellose (E464), iron oxide red (E172), iron oxide yellow (E172), macrogol (E1521), talcum (E553b) and titanium dioxide (E171)).

What AMLODIPINE/VALSARTAN BIOTECH looks like and contents of the pack
AMLODIPINE/VALSARTAN 5/160 BIOTECH: Dark yellow, oval-shaped, biconvex, film-coated tablets debossed with 'L298' on one side and plain on other side.
AMLODIPINE/VALSARTAN 10/160 BIOTECH: Light yellow, oval-shaped, biconvex, film-coated tablets debossed with 'L300' on one side and plain on other side.
AMLODIPINE/VALSARTAN 5/160 BIOTECH and AMLODIPINE/VALSARTAN 10/160 BIOTECH are packed in silver aluminium/aluminium blister strips containing 30, 90 or 100 film-coated tablets and white opaque high-density polyethylene (HDPE) round bottles with a screw cap or child resistant cap containing 30 or 500 film-coated tablets.

Holder of certificate of registration
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AMLODIPINE/VALSARTAN BIOTECH

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS
S3

AMLODIPINE/VALSARTAN 5/160 BIOTECH filmbedekte tablette (5 mg amlodipien en 160 mg valsartan)
AMLODIPINE/VALSARTAN 10/160 BIOTECH filmbedekte tablette (10 mg amlodipien en 160 mg valsartan)
Amlodipien en valsartan
Suiker vry.

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

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

1. Wat AMLODIPINE/VALSARTAN BIOTECH is en waarvoor dit gebruik word
AMLODIPINE/VALSARTAN BIOTECH bevat twee stowwe genaamd amlodipien en valsartan. Beide hierdie stowwe help om hoë bloeddruk te beheer.

Amlodipien behoort aan 'n groep stowwe wat "kalsiumkanaalblokkers" genoem word. Amlodipien keer dat kalsium in die bloedvatwand inbeweeg, wat keer dat die bloedvate toetrek.
Valsartan behoort aan 'n groep stowwe wat "angiotensien-II-reseptorantagoniste" genoem word. Angiotensien II word deur die liggaam geproduseer en laat die bloedvate styf trek en sodoende die bloeddruk verhoog. Valsartan werk deur die effek van angiotensien II te blokkeer.

Dit beteken dat albei hierdie stowwe help om te keer dat die bloedvate toetrek. As gevolg hiervan, ontspan die bloedvate en bloeddruk word verlaag.
AMLODIPINE/VALSARTAN BIOTECH word gebruik om hoë bloeddruk te behandel by volwassenes wie se bloeddruk nie genoeg beheer word met óf amlodipien óf valsartan op sy eie nie.

2. Wat jy moet weet voordat jy AMLODIPINE/VALSARTAN BIOTECH neem
Moenie AMLODIPINE/VALSARTAN BIOTECH neem nie
- Indien jy hipersensitief (allergies) is vir amlodipien of enige ander kalsiumkanaalblokkers, valsartan of vir enige van die ander bestandele van AMLODIPINE/VALSARTAN BIOTECH (gelys in afdeling 6).
- Indien jy swelling ervaar het, veral van die gesig en keel, terwyl jy ander medisyne gebruik het (insluitend angiotensienomskakelende ensieminhibeerders). As jy hierdie simptome kry, hou op om AMLODIPINE/VALSARTAN BIOTECH te neem en kontak jou dokter dadelik. Jy moet nooit weer AMLODIPINE/VALSARTAN BIOTECH neem nie.
- Indien jy herhalende episodes van erge swelling het.
- Indien jou dokter gediagnoseer het dat jy ly aan 'n vernouing van kleppe in jou hart (genoem aorta- of mitrale stenose), of abnormaal verhoogde dikte van jou hartspier met vernouing (genoem obstruktiewe hipertrofiese kardiomiopatie).
- Indien jy 'n nieroorplanting ontvang het of as jy gediagnoseer is om aan 'n vernouing van jou nierslagaar te ly of as jy aan ernstige nierprobleme ly.
- Indien jy ander medisyne of stowwe gebruik wat die kaliumvlakke in jou bloed verhoog (soos sekere tipes diuretika, kaliumaanvullings, ens.).
- Indien jy porferie het.
- Indien jy 'n medisyne neem genaamd litium.
- Indien jy diabetes of verswakte nierfunksie het en jy behandel word met 'n bloeddrukverlagende medisyne wat aliskiren bevat.
- Indien jy ernstige lewerinkorting het.
- Indien jy erge lae bloeddruk het (hipotensie).
- Indien jy kardiogeniese skok het ('n toestand waar jou hart nie in staat is om genoeg bloed aan die liggaam te verskaf nie).
- Indien jy aan hartversaking ly na 'n hartaanval.
- Indien jy swanger is of borsvoed.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met AMLODIPINE/VALSARTAN BIOTECH:
- Indien jy aliskiren neem (sien "Moenie neem nie").
- Indien jy siek was (braking of diarree).
- Indien jy 'n nieroorplanting gehad het of as jy meegedeel is dat jy 'n vernouing van jou nierslagare het.
- Indien jy lewer- of nierprobleme het.
- Indien jy 'n toestand het wat die nierkliere aantas wat "primêre hiperaldosteronisme" genoem word.
- Indien jy swelling ervaar het, veral van die gesig en keel, terwyl jy ander medisyne gebruik het (insluitend angiotensienomskakelende ensieminhibeerders). As jy hierdie simptome kry, hou op om AMLODIPINE/VALSARTAN BIOTECH te neem en kontak jou dokter dadelik. Jy moet nooit weer AMLODIPINE/VALSARTAN BIOTECH neem nie.
- Indien jy hartversaking gehad het of 'n hartaanval ervaar het. Volg jou dokter se instruksies vir die aanvangsdosis noukeurig. Jou dokter kan ook jou nierfunksie nagaan.

Kontak jou dokter om jou behandeling te herevalueer as jy met ACE-remmers/ angiotensienreseptorblokkers saam met 'n fluorokinoloon-antibiotikum behandel word.
Jou dokter kan jou nierfunksie, bloeddruk en die hoeveelheid elektroliete (bv. kalium) in jou bloed met gereelde tussenposes nagaan.

Kinders en adolessente
Die gebruik van AMLODIPINE/VALSARTAN BIOTECH in kinders en adolessente word nie aanbeveel nie (jonger as 18 jarige ouderdom).

Ander medisyne en AMLODIPINE/VALSARTAN BIOTECH
Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Vertel jou dokter indien jy die volgende neem:
- ACE-inhibeerders of aliskiren (medisyne wat gebruik word om hoë bloeddruk te behandel) (sien ook inligting onder die opskrifte "Moenie AMLODIPINE/VALSARTAN BIOTECH neem nie");
- diuretika ('n tipe medisyne wat ook "watertablette" genoem word wat die hoeveelheid uriene wat jy produseer, verhoog);
- kaliumbesparende diuretika, kaliumaanvullings, soutvervangers wat kalium bevat en ander stowwe wat kaliumvlakke kan verhoog;
- nitrogliserien en ander nitrate, of ander stowwe wat "vasodilatore" genoem word;
- medisyne wat gebruik word vir MIV/ VIGS (bv. ritonavir, indinavir, nelfinavir);
- medisyne wat gebruik word om swaminfeksies te behandel (bv. ketokonasool, itrakonasool);
- klaritromisien (vir infeksies wat deur bakterieë veroorsaak word);
- verapamil, diltiasem (hartmedisyne);
- medisyne wat gebruik word om bakteriële infeksies te behandel (soos rifampisien, eritromisien, talitromisien);
- antikonvulsiewe medisyne (bv. karbamasepien, fenobarbitoon, fenitoïen, fosfenitoïen, primidoon);
- St. John's wort;
- simvastatien ('n medisyne wat gebruik word om hoë cholesterolvlakke te beheer);
- dantroleen (infusie vir ernstige liggaamstemperatuurafwykings);
- takrolimus (gebruik om jou liggaam se immuunrespons te beheer, wat jou liggaam in staat stel om die oorgeplante orgaan te aanvaar);
- medisyne wat gebruik word om teen oorplantingverwerping te beskerm (siklosporien);
- litium ('n medisyne wat gebruik word om sekere tipes depressie te behandel) (sien ook die inligting onder "Moenie AMLODIPINE/VALSARTAN BIOTECH neem nie")
- sekere soorte pynstillers genoem nie-steroïdale anti-inflammatoriese middels (NSAID's) of selektiewe siklooksigenase-2 inhibeerders (COX-2 inhibeerders). Jou dokter kan ook jou nierfunksie nagaan.

AMLODIPINE/VALSARTAN BIOTECH met kos en drank
Pomelo en pomelosap moet nie ingeneem word deur mense wat AMLODIPINE/VALSARTAN BIOTECH neem nie. Dit is as omdat pomelo en pomelosap kan lei tot 'n verhoging in die bloedvlakke van die aktiewe stof amlodipien, wat 'n onvoorspelbare verhoging in die bloeddrukverlagende effek van AMLODIPINE/VALSARTAN BIOTECH kan veroorsaak.

Swangerskap en borsvoeding
Indien jy swanger is of borsvoed, dink dat jy mag swanger wees of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy AMLODIPINE/VALSARTAN BIOTECH neem.
Die veiligheid van AMLODIPINE/VALSARTAN BIOTECH in swanger en borsvoedende vrouens is nie vasgestel nie.
Jy moenie AMLODIPINE/VALSARTAN BIOTECH neem indien jy swanger is, probeer om swanger te raak of jou baba borsvoed nie.
Indien jy 'n vrou is van vrugbare ouderdom moet jy verseker dat jy effektiewe voorbehoeding gebruik/ toepas.

Bestuur en gebruik van masjiene
Hierdie medisyne mag jou duiselig laat voel. Dit kan affekteer hoe goed jy konsentreer.

Dit is nie altyd moontlik om te voorspel tot watter mate AMLODIPINE/ VALSARTAN BIOTECH mag inmeng met jou daaglikse aktiwiteite nie. Jy moet verseker dat jy nie 'n motor bestuur of masjinerie gebruik totdat jy bewus is van die mate waartoe AMLODIPINE/VALSARTAN BIOTECH jou affekteer nie.

3. Hoe om AMLODIPINE/VALSARTAN BIOTECH te neem
Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd AMLODIPINE/VALSARTAN BIOTECH presies soos jou dokter jou opdrag gegee het. Raadpleeg jou dokter of apteker indien jy nie seker is nie.

Die gewone dosis van AMLODIPINE/VALSARTAN BIOTECH is een tablet per dag.
- Dit word verkies dat jy jou medisyne op dieselfde tyd elke dag neem.
- Sluk die tablette met 'n glas water.
- Jy kan AMLODIPINE/VALSARTAN BIOTECH met of sonder voedsel neem. Moenie AMLODIPINE/VALSARTAN BIOTECH met pomelo of pomelosap neem nie.

Afhangende van hoe jy reageer op die behandeling mag jou dokter dalk 'n hoë of laer dosis voorstel.

Moenie die voorgeskryfde dosis oorskry nie.

AMLODIPINE/VALSARTAN BIOTECH en ouer persone (65 jaar oud en ouer)
Jou dokter moet versigtig wees wanneer jou dosis verhoog word.

Indien jy meer AMLODIPINE/VALSARTAN BIOTECH neem as wat jy moet
Oortollige vloeistof kan ophoop in jou longe (pulmonêre edeem) wat asemtekort veroorsaak wat eers later mag ontwikkel (24 – 48 ure na inname). Jy mag ophou om asem te haal en moet geventileer word.

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 AMLODIPINE/VALSARTAN BIOTECH te neem
Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

Indien jy ophou om AMLODIPINE/VALSARTAN BIOTECH te neem
Die staking van jou behandeling met AMLODIPINE/VALSARTAN BIOTECH mag veroorsaak dat jou siekte erger word. Moenie ophou om jou medisyne te neem nie, tensy jou dokter jou opdrag gee.

4. Moontlike newe-effekte
AMLODIPINE/VALSARTAN BIOTECH kan newe-effekte hê.
Nie alle newe-effekte wat vir AMLODIPINE/VALSARTAN BIOTECH aangemeld is word in hierdie pamflet bevat nie. Sou jou algemene gesondheid versleg of indien jy enige ongewensde effekte ervaar terwyl jy AMLODIPINE/VALSARTAN BIOTECH neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om AMLODIPINE/ VALSARTAN BIOTECH te neem en vertel jou dokter onmiddelik of gaan na die ongevalle-afdeling van jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat moeilike sluk en moeilike asemhaling mag veroorsaak;
- veluitslag of jeuk;
- floute.

Hierdie is almal baie ernstige newe-effekte. Indien hy hulle het, mag jy dalk 'n ernstige allergiese reaksie vir AMLODIPINE/VALSARTAN BIOTECH gehad het. Jy mag dalk dringende mediese aandag of hospitalisasie benodig.

Vertel jou dokter onmiddelik of gaan na die ongevalle-afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:
- skielike hyging, borspyn, kort van asem of moeilike asemhaling;
- ernstige velreaksies insluitende intense veluitslag, korwe, rooiheid van die vel oor jou hele liggaam, erge jeuk, blasies, afskilfering en swelling van die vel, inflammasie van die slymvliese (Stevens Johnson se Syndrome, toksiese epidermale nekrolise) of ander allergiese reaksies;
- ontsteekte pankreas wat ernstige maag- en rugpyn kan veroorsaak wat gepaardgaan met die gevoel van onwel wees;
- hartaanval, abnormale hartklop;
- boonste lugweg swelling.

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

Vertel jou dokter indien jy enige van die volgende opmerk
Gereelde newe-effekte
- influenza (griep); geblokte neus, seer keel en ongemak wanneer jy sluk;
- lae kalium vlakke;
- hoofpyn;
- astenie (swakheid);
- duiseligheid;
- maagpyn;
- siek gevoel (naarheid),
- moegheid;
- swelling van die gesig;
- rooiheid en warm gevoel van die gesig en/of nek;
- swelling in die liggaam wat veroorsaak word deur 'n oormaat vloeistof. Dit affekteer gereeld die laer liggaam soos die bene, voete en enkels, maar dit kan enige plek voorkom.

Minder gereelde newe-effekte
- gebrek aan eetlus;
- hoë kalsium, suiker, cholesterol en uriensuurvlakke in die bloed;
- lae vlakke van natrium in die bloed;
- angstige gevoel;
- abnormale koördinasie;
- lomerigheid, tinteling of gevoelloosheid van die hande of voete;
- visie versteuring en inkorting;
- lui in jou ore, kop wat draai;
- vinnige hartklop insluitend hartkloppings;
- lae bloeddruk en lighoofdigheid wanneer jy opstaan;
- hoes, nies/ loopneus veroorsaak deur inflammasie van die voering van die neus (rinitis);
- keelpyn;
- hardlywigheid, verandering in derm gewoonte;
- diarree, droë mond;
- naarheid, braking, slegte spysvertering;
- oormatige sweet;
- rooiheid van die vel;
- veluitslag ooral oor jou liggaam;
- swelling van die gewrigte;
- rugpyn, pyn in gewrigte, spierspasmas;
- sensasie van 'swaarheid';
- uitskeiding van meer uriene as normaalweg of meer drang voel om te urineer;
- onvermoë om 'n ereksie te kry of in stand te hou;
- 'n lae vlak van witbloedselle in die bloed;
- lae bloedplaatjie telling;
- oormatige suiker in bloed (hiperglukemie);
- gemoedsveranderinge, depressie, verwarring;
- smaakafwykings, verlies van pynsensasie, abnormale sensasie, tipies tinteling of prik ('spelde en naalde'), hoë vlak van spiertonus;
- bewing, slapeloosheid, gedeeltelike of totale verlies van sensasie in 'n deel van jou liggaam;
- 'n inflammasie van die bloedvate wat veranderinge in die bloedvatwande veroorsaak;
- swelling van die tandvleis;
- abdominale opgeblasenheid (gastritis), verhoogde lewerensiemverhoging wat 'n uitwerking op sommige mediese toetse kan hê;
- abnormale lewerfunksie, inflammasie van die lewer (hepatitis), vergeling van die vel (geelsug);
- haarverlies;
- velverkeuring;
- vel sensitiwiteit vir lig, pers kolle onder die vel, korwe;
- ongemak of vergroting van die borste in mans;
- gebrek aan energie;
- borspyn, onwel gevoel;
- pyn;
- gewigsverlies of gewig optel.

Indien jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, lig asseblief jou dokter of apteker daarvan in.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA aanmeld deur die vorm **"6.04 Adverse Drug Reactions Reporting Form"**, wat aanlyn onder SAHPRAf se publikasies gevind kan word: http://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld kan jy help om meer inligting oor die veiligheid van AMLODIPINE/VALSARTAN BIOTECH te verskaf.

5. Hoe om AMLODIPINE/VALSARTAN BIOTECH te bewaar
- Bewaar teen of benede 25 °C.
- Beskerm teen vog.
- Stulpstroke: hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
- HDPE bottels: Hou in die buitenste houer totdat dit benodig word vir gebruik.
- Bewaar alle medisyne buite bereik van kinders.
- Moenie gebruik na die vervaldatum wat op die stulpstrook/ ettiket/ karton gedruk is nie.
- Gee alle ongebruikte medisyne terug aan jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelses (bv toilette) weggooi nie.

6. Inhoud van die pak en ander inligting
Wat AMLODIPINE/VALSARTAN BIOTECH bevat
AMLODIPINE/VALSARTAN BIOTECH 5/160: Elke filmbedekte tablet bevat 6,9 mg amlodipienbesilaat (gelykstaande aan 5 mg amlodipien) en 160 mg valsartan.
AMLODIPINE/VALSARTAN BIOTECH 10/160: Elke filmbedekte tablet bevat 13,9 mg amlodipienbesilaat (gelykstaande aan 10 mg amlodipien) en 160 mg valsartan.
Die ander bestandele is kolloïdale silikondioksied (E551), kruispovidoon (E1201), magnesiumstereaat (E572), mikrokristallyne sellulose (E460(i)), Opadry Geel (wat hipromellose (E464), rooi ysteroksied (E172), geel ysteroksied (E172), makrogol (E1521), talkum (E553b) en titaandioksied (E171) bevat).

Hoe AMLODIPINE/VALSARTAN BIOTECH lyk en die inhoud van die pak
AMLODIPINE/VALSARTAN 5/160 BIOTECH: Donker geel, ovaalvormige, bikonvekse, filmbedekte tablette met 'L298' aan die een kant gedruk en ongedruk aan die ander kant.
AMLODIPINE/VALSARTAN 10/160 BIOTECH: Liggeel, ovaalvormig, bikonvekse, filmbedekte tablette met 'L300' aan die een kant gedruk en ongedruk aan die ander kant.
AMLODIPINE/VALSARTAN 5/160 BIOTECH en AMLODIPINE/VALSARTAN 10/160 BIOTECH word verpak in silver aluminium/aluminium stulpstroke wat 30, 90 of 100 filmbedekte tablette bevat en wit ondeursigtige hoë-densiteit poliëtileen (HDPE) ronde bottels met 'n skroefdop of 'n kinderweerstandige dop wat 30 of 500 filmbedekte tablette bevat.

Houer van die sertifikaat van registrasie
Biotech Laboratories (Edms.) Bpk
Grondvloer, Blok K Wes, Central park
16de Weg 400, Randjespark
Midrand 1685
011 848 3050

Hierdie pamflet is laas hersien
24 Mei 2023.

Registrasienommers
AMLODIPINE/VALSARTAN 5/160 BIOTECH: 50/7.1.3/0851
AMLODIPINE/VALSARTAN 10/160 BIOTECH: 50/7.1.3/0852

Datum van registrasie
11 May 2021