Grain Direction

300 mm

AMLOVASC TABLETS
5 mg / 10 mg
PM04139602

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

AMLOVASC TABLETS 5 mg
AMLOVASC TABLETS 10 mg
Amlodipine (as besilate)
Sugar free

Read all of this leaflet carefully before you start taking AMLOVASC TABLETS
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- **AMLOVASC TABLETS** 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 **AMLOVASC TABLETS** is and what it is used for
2. What you need to know before you take **AMLOVASC TABLETS**
3. How to take **AMLOVASC TABLETS**
4. Possible side effects
5. How to store **AMLOVASC TABLETS**
6. Contents of the pack and other information

1. What AMLOVASC TABLETS is and what it is used for

AMLOVASC TABLETS contains the active substance amlodipine which belongs to a group of medicines called selective calcium channel blockers.
AMLOVASC TABLETS is used to treat high blood pressure (hypertension) and to treat chest pain or discomfort, called angina pectoris. Your doctor may prescribe you **AMLOVASC TABLETS** together with other medicines used to lower your blood pressure.

2. What you need to know before you take AMLOVASC TABLETS

Do not take AMLOVASC TABLETS
- If you are hypersensitive (allergic) to amlodipine, other calcium channel blockers or any of the other ingredients of **AMLOVASC TABLETS** listed in section 6 of this leaflet.
- If you have severe low blood pressure.
- If you have had shock or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- If you have aortic stenosis (narrowing of the heart valve of the aorta).
- If you recently suffered a heart attack (within the past 28 days).
- If you have been diagnosed with unstable angina (chest pain occurring while resting).
- If you are pregnant or breastfeeding.

Warnings and precautions
*Tell your doctor before taking **AMLOVASC TABLETS** :*
- If you suffer from heart failure.
- If you have been diagnosed with aortic stenosis (narrowing of the aortic heart valve).
- If you have severe liver problems. Your doctor may need to monitor your liver function and adjust your dose of **AMLOVASC TABLETS** accordingly.
- If you are 65 years or older.
- If you suffer from severe kidney problems.
- If you suffer from diabetes.
- If you have porphyria (a group of disorders that result in a buildup of natural chemicals called porphyrins in your body).
- If you experience chest pain while taking **AMLOVASC TABLETS.**
- If you have low blood pressure.

Children and adolescents
Do not give **AMLOVASC TABLETS** to children and adolescents as safety and efficacy have not been established.

Other medicines and AMLOVASC TABLETS
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

*Tell your doctor or pharmacist before you take **AMLOVASC TABLETS** if you are taking:*
- Protease inhibitors (used to treat human immunodeficiency virus (HIV)).
- Azole antifungals, such as itraconazole or ketoconazole (used to treat fungal infections).
- Macrolide antibacterials, such as erythromycin or clarithromycin (used to treat bacterial infections).
- Verapamil (used to treat high blood pressure and heart pain) or any medicine that may lower your blood pressure.
- Diltiazem (used to treat chest pain).
- Rifampicin (used to treat tuberculosis (TB) or certain other bacterial infections).
- St. John's Wort (herbal medicine).
- Carbamazepine, phenobarbitone, phenytoin or valproate (used to treat seizures (fits)).
- Dantrolene (used to treat severe body temperature abnormalities).
- Medicines for treating angina (chest pains), such as nitro-glycerine or beta-blockers.
- Tacrolimus (used to treat eczema or during organ transplants).
- Mammalian target of rapamycin (mTOR) inhibitors, such as temsirolimus, everolimus and sirolimus (used to treat cancer).
- Simvastatin (used to lower fat in your blood).
- Quinidine or procainamide (used to treat heart rhythm disorders).
- Lithium (used to treat some types of depression).

Tell your doctor or pharmacist before you take **AMLOVASC TABLETS** if you have

While taking **AMLOVASC TABLETS**, you should avoid consuming grapefruit juice or grapefruits as it may increase the risk of your blood pressure lowering more than expected.

Pregnancy, breastfeeding and fertility
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 **AMLOVASC TABLETS.**
You should not take **AMLOVASC TABLETS** if you are pregnant or breastfeeding.

Driving and using machines
AMLOVASC TABLETS may cause dizziness, tiredness, nausea (feeling sick) or headaches, which may affect your ability to drive or use machines. You may experience these effects more at the start of your treatment with **AMLOVASC TABLETS**. Do not drive or operate machinery until you know how **AMLOVASC TABLETS** affects you.

3. How to take AMLOVASC TABLETS

Do not share medicines prescribed for you with any other person.
Always take **AMLOVASC TABLETS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
The usual dose is one tablet of **AMLOVASC TABLETS 5 mg** or one tablet of **AMLOVASC TABLETS 10 mg** once a day taken orally.
Your doctor will determine your dose based on your age, liver function or your response to **AMLOVASC TABLETS.**
AMLOVASC TABLETS can be taken with or without food.
Your doctor will tell you how long your treatment with **AMLOVASC TABLETS** will last.
If you have the impression that the effect of **AMLOVASC TABLETS** is too strong or too weak, tell your doctor or pharmacist.
Taking your tablets at the same time each day will have the best effect on your blood pressure. It will also help you remember when to take the tablets.

If you take more AMLOVASC TABLETS than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take along any tablets that are left, including the carton, so that the hospital staff can easily tell what you have taken.

If you forget to take AMLOVASC TABLETS
If you forget to take a dose, take it as soon as you remember unless it is nearly time to take your next dose. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

AMLOVASC TABLETS can have side effects.
Not all side effects reported for **AMLOVASC TABLETS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **AMLOVASC TABLETS**, please consult your health care provider for advice.

If any of the following happens, stop taking **AMLOVASC TABLETS** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of your hands, feet, ankles, face, lips 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 **AMLOVASC TABLETS**. 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:
- changes in the way your heart beats (irregular heartbeats, beating slower or faster than usual) or heart attack;
- painful, blistering or peeling skin rash;
- bleeding or bruising more easily than normal or abnormal blood test results;
- frequent infections such as fever, severe chills, sore throat or mouth ulcers;
- yellowing of your skin and eyes, also called jaundice or hepatitis;
- pancreatitis (nausea, vomiting, fever, pain in your stomach area radiating to your back);
- erythema multiforme (red, often itchy spots, similar to the rash of measles which starts on the limbs and sometimes on the face and the rest of the body, the spots may blister or may progress to form raised, red, pale-centred marks, other symptoms include fever, sore throat, headache and/or diarrhoea);
- difficulty breathing or chest pain.

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
- water retention (causing swelling of your ankles, hands and feet);
- visual disturbance (seeing double);
- sleepiness, dizziness or headaches (especially when you first start taking **AMLOVASC TABLETS**);
- pain in your stomach area, nausea (feeling sick), feeling bloated (caused by excessive gas) and indigestion;
- changes in bowel movements, such as constipation or diarrhoea;
- muscle cramps, physical weakness and lack of energy;
- flushing of your skin (blushing).

Less frequent side effects
- bleeding or small pin-sized purple spots on the skin;
- increased blood sugar levels;
- changes in test results when your doctor monitors your liver function;
- a decrease in blood pressure (causing light-headedness, clammy skin, nausea and dizziness);
- vasculitis (fever, headache, fatigue, weight loss, general aches and pains, night sweats, nerve problems such as numbness or weakness);
- changes in the frequency or control of urination, urinating more at night;
- numbness, a loss of sensation, tingling or numbness in your hands or feet, feeling of weakness or heaviness in your arms and legs;
- stiffness of your muscles and joint, muscle or back pain, pain in a joint and feeling unwell;
- vomiting (being sick), a dry mouth or gastritis (causing pain, nausea, vomiting, vomiting blood, blood in the stool);
- overgrowth of the gums (causing pain, swelling and bad breath);
- distortion of the sense of taste;
- coughing or a runny nose;
- breast enlargement in men;
- problems with sexual performance;
- hair loss or excessive sweating;
- discolouration of the skin or sensitivity to the sun;
- gaining or losing weight.

Side effects with an unknown frequency
- muscle spasms, slow movement and irregular, jerky movements.

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 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 **AMLOVASC TABLETS.**

5. How to store AMLOVASC TABLETS

Store at or below 25 °C (room temperature).
Keep the container closed tightly. Keep the blister in the carton until required for use.
Store in the original package in order to protect from light.
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
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 AMLOVASC TABLETS contains
The active substance in **AMLOVASC TABLETS** is amlodipine.
AMLOVASC TABLETS 5 mg: Each tablet contains 5 mg amlodipine (as amlodipine besilate).
AMLOVASC TABLETS 10 mg: Each tablet contains 10 mg amlodipine (as amlodipine besilate).
The other ingredients are: Anhydrous dibasic calcium phosphate, magnesium stearate, microcrystalline cellulose and sodium starch glycolate.

What AMLOVASC TABLETS looks like and contents of the pack
AMLOVASC TABLETS 5 mg
White to off white, capsule shaped, biconvex, uncoated tablets, debossed, "ML22" on one side and plain on other side.
AMLOVASC TABLETS 10 mg
White to off white, round, biconvex, uncoated tablets, debossed, "ML23" on one side and plain on other side
Blister pack:
Amber coloured 250 µ PVC/ 90 gsm PVdC as the forming material and silver coloured plain 25 µ aluminium foil/ 6-8 gsm HSL as the lidding material, packed in a pre-printed unit carton. Pack sizes 28's, 30's and 100's.
HDPE container pack:
Round, white, HDPE container (40 ml for **AMLOVASC TABLETS 5 mg** and 60 ml for **AMLOVASC TABLETS 10 mg**) with 33 mm neck finish, containing 90's tablets, closed with a white polypropylene child resistant closure, 33 mm with white printed pulp and heat seal liner and packed in a pre-printed unit carton. Pack size 90's.
Not all packs and pack sizes are necessarily marketed.

Holder of certificate of registration
MACLEODS PHARMACEUTICALS SA (PTY) LTD
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Access to the corresponding Professional Information
The corresponding professional information can be accessed at macleodssaproducts.co.za or contact 011 682 1169

300 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S3

AMLOVASC TABLETS 5 mg
AMLOVASC TABLETS 10 mg
Amlodipien (as besilaat)
Suikervry

Lees hierdie inligtingstuk sorgvuldig voordat jy AMLOVASC TABLETS begin gebruik
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidso rgverskaffer indien jy verdere vrae het.
- **AMLOVASC TABLETS** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat in hierdie inligtingstuk is

1. Wat **AMLOVASC TABLETS** is en waarvoor dit gebruik word.
2. Wat jy behoort te weet voordat jy **AMLOVASC TABLETS** gebruik.
3. Hoe om **AMLOVASC TABLETS** te gebruik.
4. Moontlike newe-effekte.
5. Hoe om **AMLOVASC TABLETS** te bewaar.
6. Inhoud van die pak en ander inligting.

1. Wat AMLOVASC TABLETS is en waarvoor dit gebruik word

AMLOVASC TABLETS bevat die aktiewe bestanddeel amlodipien wat aan 'n groep medisyne behoort wat selektiewe kalsiumkanaalblokkers genoem word.
AMLOVASC TABLETS word gebruik om hoë bloeddruk (hipertensie) te behandel en om borskaspyn of ongemak, genoem angina pectoris, te behandel. Jou dokter kan vir jou **AMLOVASC TABLETS** voorskryf saam met ander medisyne wat gebruik word om jou bloeddruk te verlaag.

2. Wat jy behoort te weet voordat jy AMLOVASC TABLETS gebruik

Moet nie AMLOVASC TABLETS gebruik
- Indien jy hipersensitief (allergies) vir amlodipien, ander kalsiumkanaalblokkers of enige van die ander bestanddele van **AMLOVASC TABLETS**, wat in afdeling 6 van hierdie inligtingstuk gelys word, is nie.
- Indien jy ernstige lae bloeddruk het nie.
- As jy skok of kardiogene skok gehad het nie ('n toestand waar jou hart nie in staat is om genoeg bloed aan die liggaam te voorsien nie).
- Indien jy aortastenose het (vernouing van die hartklep van die aorta).
- As jy onlangs 'n hartaanval gehad het (binne die laaste 28 dae).
- Indien jy gediagnoseer is met onstabiele angina (borskaspyn wat tydens rus voorkom).
- As jy swanger is of borsvoed.

Waarskuwings en voorsorgmaatreëls
*Vertel jou dokter voordat jy **AMLOVASC TABLETS** neem:*
- Indien jy aan hartversaking ly.
- Indien jy gediagnoseer is met aortastenose (vernouing van die aorta-hartklep).
- As jy ernstige lewerprobleme het. Jou dokter mag nodig hê om jou lewerfunksie te monitor en jou dosering van **AMLOVASC TABLETS** dienooreenkomstig aan te pas.
- As jy 65 jaar of ouer is.
- Indien jy aan ernstige nierprobleme ly.
- Indien jy aan diabetes ly.
- As jy porfirie het ('n groep versteurings wat lei tot 'n opbou van natuurlike chemikalieë naamlik porfiriene in jou liggaam).
- Indien jy borskaspyn ervaar terwyl jy **AMLOVASC TABLETS** neem.
- As jy lae bloeddruk het.

Kinders en adolessente
Moet nie **AMLOVASC TABLETS** aan kinders en adolessente gee nie aangesien veiligheid en doeltreffendheid nie vasgestel is nie.

Ander medisyne en AMLOVASC TABLETS
Vertel altyd vir jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)

*Vertel jou dokter of apteker, voordat jy **AMLOVASC TABLETS** neem, indien jy van die volgende middels gebruik :*
- Protease-inhibeerders (gebruik om menslike immuniteitsgebrekvirus (MIV) te behandel).
- Asool swambestrydende middels, soos itrakonasool of ketokonasool (word gebruik om swaminfeksies te behandel).
- Makrolied antibakteriese middels, soos eritromisien of klaritromisien (word gebruik om bakteriële infeksies te behandel).
- Verapamil (gebruik om hoë bloeddruk en hartpyn te behandel) of enige medisyne wat jou bloeddruk kan verlaag.
- Diltiasem (word gebruik om borskaspyn te behandel).
- Rifampisien (gebruik om tuberkulose (TB) of sekere ander bakteriële infeksies te behandel).
- St. Johannes Kruid (kruie medisyne).
- Karbamasepien, fenobarbitoon, fenitoïen of valproaat (gebruik om aanvalle (stuipe) te behandel).
- Dantroleen (gebruik om erge liggaamstemperatuur afwykings te behandel).
- Medisyne vir die behandeling van angina (borskaspyne), soos nitrogliserien of betablokkers.
- Takrolimus (gebruik om ekseem te behandel of tydens orgaanoorplantings).
- Soogdierteiken van rapamisien (mTOR) inhibeerders, soos temsirolimus, everolimus en sirolimus (gebruik om kanker te behandel).
- Simvastatien (gebruik om vet in jou bloed te verlaag).
- Kinidien of prokaïenamied (gebruik om hartritme versteurings te behandel).

bloed te monitor en jou dosering van siklosporien aan te pas volgens die toetsresultate.

AMLOVASC TABLETS met voedsel en drank
Terwyl jy **AMLOVASC TABLETS** neem, moet jy die inname van pomelosap of pomelo's vermy, aangesien dit die risiko kan verhoog dat jou bloeddruk kan verlaag, meer as wat verwag word.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, dink dat jy moontlik swanger is of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy **AMLOVASC TABLETS** neem.
Jy moet nie **AMLOVASC TABLETS** neem indien jy swanger is of borsvoed nie.

Bestuur en gebruik van masjinerie
AMLOVASC TABLETS kan duiseligheid, moegheid, naarheid (siek voel) of hoofpyne veroorsaak, wat jou vermoë om te bestuur of masjinerie te gebruik, kan beïnvloed. Jy kan hierdie effekte meer ervaar met die aanvang van jou behandeling met **AMLOVASC TABLETS**. Moet nie bestuur of masjinerie bedryf totdat jy weet hoe **AMLOVASC TABLETS** jou affekteer nie.

3. Hoe om AMLOVASC TABLETS te gebruik

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **AMLOVASC TABLETS** presies soos jou dokter jou beveel het. Vra vir jou dokter of apteker indien jy onseker is.
Die gewone dosis is een tablet **AMLOVASC TABLETS 5 mg** of een tablet **AMLOVASC TABLETS 10 mg** een keer per dag, oraal geneem.
Jou dokter sal jou dosis bepaal gebaseer op jou ouderdom, lewerfunksie of jou reaksie op **AMLOVASC TABLETS**.
AMLOVASC TABLETS kan met óf sonder kos geneem word.
Jou dokter sal vir jou sê hoe lank jou behandeling met **AMLOVASC TABLETS** sal duur.
Indien jy onder die indruk is dat die effek van **AMLOVASC TABLETS** te sterk of te swak is, sê vir jou dokter of apteker.
Om jou tablette elke dag op dieselfde tyd te neem sal die beste uitwerking op jou bloeddruk hê. Dit sal jou ook help om te onthou wanneer om die tablette te neem.

Indien jy meer AMLOVASC TABLETS geneem het as wat jy behoort te neem
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum. Neem enige oorblywende tablette, insluitend die karton saam, sodat die hospitaalpersoneel maklik kan vasstel wat jy geneem het.

Indien jy vergeet om AMLOVASC TABLETS te neem
Indien jy vergeet om 'n dosis te neem, neem dit so gou as wat jy onthou, tensy dit amper tyd is om jou volgende dosis te neem. Moet nie 'n dubbele dosis neem om vir vergete individuele dosisse op te maak nie.

4. Moontlike newe-effekte

AMLOVASC TABLETS kan newe-effekte hê.
Nie al die newe-effekte wat vir **AMLOVASC TABLETS** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid versleg of jy enige ongewenste effekte ervaar terwyl jy **AMLOVASC TABLETS** gebruik, raadpleeg jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van **AMLOVASC TABLETS** en vertel onmiddellik vir jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal:
- swelling van jou hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal;
- uitslag of gejeuk;
- flou word.

Hierdie is alles baie ernstige newe-effekte. Indien jy dit het, mag jy 'n ernstige reaksie teen **AMLOVASC TABLETS** gehad het. Jy mag dringende mediese aandag of hospitalisasie nodig hê.

Vertel jou dokter onmiddellik of gaan na die ongevalle afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:
- veranderinge in die manier waarop jou hart klop (onreëlmatige hartklop, klop stadiger of vinniger as gewoonlik) of hartaanval;
- pynlike, blaasvormige of afskilferende veluitslag;
- bloeding of kneusing baie makliker as normaal of abnormale bloedtoetsresultate;
- gereelde infeksies soos koors, erge koue rillings, seer keel of mondsere;
- geelwording van jou vel en oë, ook genoem geelsug of hepatitis;
- pankreatitis (naarheid, braking, koors, pyn in jou maagarea wat na jou rug uitstraal);
- veelvuldige eriteem (rooi, dikwels jeukerige kolle, soortgelyk aan die uitslag van masels wat op die ledemate begin en soms op die gesig en die res van die liggaam, die kolle kan blase vorm of kan vorder om verhewe, rooi, bleek-gesentreerde merke te vorm, ander simptome sluit koors, seer keel, hoofpyn en/of diaree in);
- moeilike asemhaling of borskaspyn.

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

Sê vir jou dokter indien jy enige van die volgende waarneem:
Gereelde newe-effekte
- waterretensie (wat swelling van jou enkels, hande en voete veroorsaak);
- versteurde visie (sien dubbel);
- slaperigheid, duiseligheid of hoofpyn (veral wanneer jy vir die eerste keer begin om **AMLOVASC TABLETS** te neem);
- pyn in jou maagarea, naarheid (siek voel), opgeblase gevoel (veroorsaak deur oormatige gas) en swak spysvertering;
- veranderinge in dermbewegings, soos hardlywigheid of diaree;
- spierkrampe, fisiese swakheid en gebrek aan energie;
- gloede van jou vel (blosing).
- 'n afname in bloeddruk (wat lighoofdigheid, klam vel, naarheid en duiseligheid veroorsaak);
- vaskulitis (koors, hoofpyn, vermoeidheid, gewigsverlies, algemene skete en pyne, nagsweet, senuweeprobleme soos gevoelloosheid of swakheid);
- veranderinge in die frekwensie of beheer van urinering, urineer meer in die nag;
- depressief of verward voel, veranderinge in jou bui, angstigheid en slaaploosheid;
- bewerasie (bewing);
- gesuis in die ore;
- gevoelloosheid, 'n verlies aan sensasie, tinteling of gevoelloosheid in jou hande of voete, gevoel van swakheid of 'n swaar gevoel in jou arms en bene;
- styfheid van jou spiere en gewrig, spier- of rugpyn, pyn in 'n gewrig en voel nie wel nie;
- braking (siek wees), 'n droë mond of gastritis (wat pyn, naarheid, braking, bloed opbraak, bloed in die stoelgang veroorsaak);
- oorgroei van die tandvleis (wat pyn, swelling en slegte asem veroorsaak);
- verandering van die smaaksin;
- hoes of 'n loopneus;
- vergroting van borste by mans;
- probleme met seksuele prestasie;
- haarverlies of oormatige sweet;
- verkleuring van die vel of sensitiwiteit vir die son;
- toename of verlies van gewig.

Newe-effekte met onbekende frekwensie
- spierspasmas, stadige beweging en onreëlmatige, rukkerige bewegings.

Lig asseblief jou dokter of apteker in indien jy enige newe-effek ervaar wat nie in hierdie inligtingstuk genoem word nie.

Aanmelding van newe-effekte
Indien jy newe-effekte kry praat met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via 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 aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **AMLOVASC TABLETS**.

5. Hoe om AMLOVASC TABLETS te bewaar

Bewaar by of benede 25°C (kamertemperatuur).
Hou die houer dig toe. Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik. Bewaar in die oorspronklike verpakking om sodoende teen lig te beskerm.
BEWAAR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat AMLOVASC TABLETS bevat
Die aktiewe bestanddeel in **AMLOVASC TABLETS** is amlodipien.
AMLOVASC TABLETS 5 mg: Elke tablet bevat 5 mg amlodipien (as amlodipienbesilaat).
AMLOVASC TABLETS 10 mg: Elke tablet bevat 10 mg amlodipien (as amlodipienbesilaat).
Die ander bestanddele is: Anhidriese dibasiese kalsiumfosfaat, magnesiumstearaat, mikrokristallyne sellulose en natriumstyselglikolaat.

Hoe AMLOVASC TABLETS lyk en inhoud van die pak
AMLOVASC TABLETS 5 mg
Wit tot naaswit, kapsuulvormige, bikonvekse, onbedekte tablette, met "ML22" aan die een kant gedruk en gewoon aan die ander kant.
AMLOVASC TABLETS 10 mg
Wit tot naaswit, ronde, bikonvekse, onbedekte tablette, met "ML23" aan die een kant gedruk en gewoon aan die ander kant.
Stulpverpakking:
Amberkleurige 250 µ PVC/ 90 gsm PVdC as die vormingsmateriaal en silwerkleurige eenvoudige 25 µ aluminiumfoelie/ 6-8 gsm HSL as die dekmateriaal, verpak in 'n voorafgedrukte eenheidskarton. Verpakkings groottes 28's, 30's en 100's.
HDPE houer verpakking:
Ronde, wit HDPE houer (40 ml vir **AMLOVASC TABLETS** 5 mg en 60 ml vir **AMLOVASC TABLETS** 10 mg) met 33 mm nekafwerking, wat 90's tablette bevat, gesluit met wit 'n polipropileen kinderbestande sluiting, 33 mm met wit gedrukte pulp en hitte seël voering en verpak in 'n voorafgedrukte eenheidskarton. Verpakkings grootte 90's.
Nie alle verpakkings en verpakkings groottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat
MACLEODS PHARMACEUTICALS SA (Edms) Bpk
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia Weg 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid Afrika

Hierdie inligtingstuk was laas hersien in
Datum van eerste goedkeuring: 07 Desember 2021
Datum van hersiening: Word tydens hersiening deur SAHPRA toegeken

Registrasienommer
AMLOVASC TABLETS 5 mg : 51/7.1/0026
AMLOVASC TABLETS 10 mg : 51/7.1/0027

Vir die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan by macleodssaproducts.co.za verkry word of deur 011 682 1169 te kontak.

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Dimensions change

1. Product: Amlovasc Tablets 5/10 mg (Amlodipine 5/10 mg)	
2. Country: South Africa(Private South Africa)	3. Packaging component: Patient Information
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	8. Dimensions: 335 (L) x 300 (W) mm
9. Design / Style: Booklet	10. Item code No.: PM04139602
11. Artwork has been made: Actual Size	12. Pharma code No.: 34225 mini
13. Barcode/NDC No: NA	14. Supersedes Item code No: PM04139601
15. Revision no: 01	16. A/W File name:X:\Amlodipine Besylate\Private South Africa\02\AMLOVASC TABLETS 10 mg PIL - PM04139602.cdr
Approved By:	17. Location: Daman

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
09/09/24		09/09/24	09/09/24	10/09/24	10/09/24

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-01

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa (Private South Africa)	PM04139601	02/05/23	Not Implimented
2) Dimensions change	PM04139602		