Front Side

280 mm

ARLOZYB
5/160, 10/160
(film-coated tablet)
PM03929602

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

ARLOZYB 5/160 tablet (5 mg amlodipine and 160 mg valsartan)
ARLOZYB 10/160 tablet (10 mg amlodipine and 160 mg valsartan)
Sugar free

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

1. What ARLOZYB is and what it is used for

ARLOZYB tablets contain 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.

ARLOZYB 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 ARLOZYB

Do not take **ARLOZYB**:
- If you are hypersensitive (allergic) to amlodipine or any other calcium channel blockers, valsartan or to any of the other ingredients of **ARLOZYB** (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 **ARLOZYB** and contact your doctor straight away. You should never take **ARLOZYB** again.
- If you have recurrent episodes of severe swelling
- 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 **ARLOZYB**:
- 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 **ARLOZYB** and contact your doctor straight away. You should never take **ARLOZYB** 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 **ARLOZYB** in children and adolescents is not recommended (aged below 18 years old).

Other medicines and ARLOZYB
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:
- ACE inhibitors or aliskiren (medicines used to treat high blood pressure) (see also information under the headings "Do not take **ARLOZYB**")
- 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, telithromycin
- 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 **ARLOZYB**")
- certain types of painkillers called non-steroidal anti-inflammatory medicines (NSAIDs) or selective cyclooxygenase-2 inhibitors (COX-2 inhibitors). Your doctor may also check your kidney function

ARLOZYB with food and drink
Grapefruit and grapefruit juice should not be consumed by people who are taking **ARLOZYB**. 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 **ARLOZYB**.

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 **ARLOZYB**.
Safety of **ARLOZYB** in pregnant and breastfeeding women has not been established.
You should not use **ARLOZYB** 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 **ARLOZYB** 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 **ARLOZYB** affects you.

3. How to take ARLOZYB

Do not share medicines prescribed for you with any other person.
Always take **ARLOZYB** exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of **ARLOZYB** 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 **ARLOZYB** with or without food. Do not take **ARLOZYB** 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.

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

If you take more ARLOZYB than you should
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 ARLOZYB
Do not take a double dose to make up for forgotten individual doses.

If you stop taking ARLOZYB
Stopping your treatment with **ARLOZYB** may cause your disease to get worse. Do not stop taking your medicine unless your doctor tells you to.

4. Possible side effects

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

If any of the following symptoms occur, stop taking the **ARLOZYB** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the 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 allergic reaction to **ARLOZYB**. 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
- palpitations (awareness of your heartbeat)
- 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
- loss 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 the 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,
- abdominal pain
- 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, 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 **ARLOZYB**.

5. How to store ARLOZYB

Store at or below 25 °C. Protect from light and moisture.
Store all medicines out of reach of children.
Store in the original package / container.
Keep the blisters in the carton until required for use.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister / label / carton / bottle.
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 ARLOZYB contains
The active substances are amlodipine besylate and valsartan
The other ingredients include
Tablet core
Microcrystalline cellulose, crospovidone, colloidal silicon dioxide, magnesium stearate.
Film coating contains:
Hypromellose, polyethylene glycol 400, talc, titanium dioxide (C.I. no. 77891), iron oxide yellow (C.I. no. 77492) for **ARLOZYB TABLETS** 5/160 mg and 10/160 mg and iron oxide red (C.I. no. 77491) – for **ARLOZYB TABLETS** 10/160 mg.

What ARLOZYB looks like and contents of the pack
Blister Pack: **ARLOZYB** 5/160 mg and 10/160 mg
Plain 30 micron Aluminium foil/6-8 gsm heat seal lacquer as the lidding material and Cold form laminate, 25 µ OPA/ 45 µ aluminium foil /50 µ PVC as the forming material, packed in a pre-printed unit carton.
Pack sizes 7's, 14's, 28's, 30's, 56's, 90's, 98's and 100's.

HDPE container pack: **ARLOZYB** 5/160 mg and 10/160 mg
60 ml round, white, HDPE container with 33 mm neck finish, containing 30 or 90 tablets, closed with White, polypropylene, child resistant, with pulp and white printed heat seal liner, 33 mm and packed in a pre-printed unit carton
Pack sizes 30's and 90's
Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa

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Registration number
ARLOZYB 5/160 : 50/7.1.3/0313
ARLOZYB 10/160 : 50/7.1.3/0314

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://macleodssaproducts.co.za/ **or contact 011 682 1169.**

335 mm

Back Side

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S3

ARLOZYB 5/160 tablet (5 mg amlodipien en 160 mg valsartaan)
ARLOZYB 10/160 tablet (10 mg amlodipien en 160 mg valsartaan)
Sulkervy

Lees hierdie inligtingstuk sorgvuldig voordat jy ARLOZYB begin gebruik
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het.
- **ARLOZYB** 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 **ARLOZYB** is en waarvoor dit gebruik word.
2. Wat jy behoort te weet voordat jy **ARLOZYB** neem.
3. Hoe om **ARLOZYB** te gebruik.
4. Moontlike newe-effekte
5. Hoe om **ARLOZYB** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat ARLOZYB is en waarvoor dit gebruik word

ARLOZYB tablette bevat twee bestanddele naamlik amlodipien en valsartaan. Beide hierdie bestanddele help om hoë bloeddruk te beheer.
Amlodipien behoort tot 'n groep stowwe wat "kalsiumkanaalblokkeerders" genoem word. Amlodipien keer dat kalsium in die bloedvatwand inbeweeg, wat keer dat die bloedvate toetrek.
Valsartaan behoort tot 'n groep stowwe wat "angiotensien II reseptor antagoniste" genoem word. Angiotensien II word deur die liggaam geproduseer en laat die bloedvate toetrek en sodoende verhoog die bloeddruk. Valsartaan werk deur die effek van angiotensien II te blokkeer.

Dit beteken dat albei hierdie bestanddele help om te keer dat die bloedvate toetrek. As gevolg hiervan ontspan die bloedvate en word bloeddruk verlaag.

ARLOZYB word gebruik om hoë bloeddruk te behandel in volwassenes wie se bloeddruk nie genoegsaam beheer word met amlodipien of valsartaan op sy eie nie.

2. Wat jy behoort te weet voordat jy ARLOZYB neem

Moet nie ARLOZYB gebruik nie:
- Indien jy hipersensitief (allergies) vir amlodipien, of enige ander kalsiumkanaalblokkeerders, valsartaan of vir enige van die ander bestanddele van **ARLOZYB** (gelys in in afdeling 6) is.
- Indien jy swelling ervaar het, veral van die gesig en keel, terwyl jy ander medisyne gebruik het (insluitend angiotensien omskakelende ensiem inhibeerders). As jy hierdie simptome kry, hou op om **ARLOZYB** te neem en kontak jou dokter dadelik. Jy moet nooit weer **ARLOZYB** neem nie.
- Indien jy herhalende episodes van erge swelling het.
- Jou dokter gediagnoseer het dat jy aan 'n vernouing van kleppe in jou hart ly (genoem aorta- of mitraal stenose), of abnormaal verhoogde dikte van jou hartspier met vernouing het (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 bestanddele gebruik wat die kaliumvlakke in jou bloed verhoog (soos sekere soorte van diuretika, kaliumaanvullings, ens.);
- Indien jy porfirie het;
- Indien jy 'n medisyne genaamd litium neem;
- Indien jy behandel word met 'n bloeddruk verlagende medisyne wat aliskiren bevat;
- Indien jy ernstige lewerinkorting het;
- Indien jy ernstige lae bloeddruk (hipotensie) het;
- Indien jy kardiogene skok het ('n toestand waar jou hart nie in staat is om genoeg bloed aan die liggaam te kan voorsien nie);
- Indien jy aan hartversaking ly na 'n hartaanval;
- Indien jy swanger is of borsvoed.

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met **ARLOZYB**:
- Indien jy aliskiren neem (sien "Moet nie 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 renale kliere aantas naamlik "primêre hiperaldosteronisme";
- indien jy swelling ervaar het, veral van die gesig en keel, terwyl jy ander medisyne gebruik het (insluitend angiotensien omskakelende ensiem inhibeerders). As jy hierdie simptome kry, hou op om **ARLOZYB** te neem en kontak jou dokter onmiddellik. Jy moet nooit weer **ARLOZYB** neem nie;
- Indien jy hartversaking gehad het of 'n hartaanval ervaar het. Volg jou dokter se instruksies noukeurig vir die aanvangsdosis. Jou dokter kan ook jou nierfunksie nagaan.

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

Kinders en adolessente
Die gebruik van **ARLOZYB** in kinders en adolessente word nie aanbeveel nie (jonger as 18 jaar oud).

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

Vertel jou dokter indien jy van die volgende middels gebruik:
- AOE-inhibeerders of aliskiren (medisyne wat gebruik word om hoë bloeddruk te behandel) (sien ook inligting onder die opskrifte "Moet nie **ARLOZYB** neem nie");
- diuretika ('n soort medisyne wat ook "watertablette" genoem word wat die hoeveelheid uriene wat jy produseer, verhoog);
- kaliumsparende diuretika, kaliumaanvullings, soutvervangers wat kalium bevat en ander stowwe wat kaliumvlakke kan verhoog;
- nitrogliserien en ander nitrate, of ander stowwe wat "vasodilators" 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 bakteriës veroorsaak word);
- verapamil, diltiasem (hartmedisyne);
- medisyne wat gebruik word om bakteriële infeksies te behandel (soos rifampisien, eritromisien, telitromisien);
- stuipwerende medisyne (bv. karbamasepien, fenobarbitoon, fenitoïen, fosfenitoïen, primidoon);
- St. Johannes se kruid;
- simvastatien ('n medisyne wat gebruik word om hoë cholesterolvlakke te beheer);
- dantroleen (infusie vir ernstige liggaamstemperatuur abnormaliteite);
- 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 toon oorplantingsverwerping te beskerm (siklosporien);
- litium ('n medisyne wat gebruik word gebruik om sommige soorte depressie te behandel) (sien ook inligting onder die opskrifte "Moet nie **ARLOZYB** neem nie");
- sekere soorte pynstillers naamlik nie-steroïdale anti-inflammatoriese medisyne (NSAIM's) of selektiewe siklooksigenase-2 inhibeerders (COX-2 inhibeerders). Jou dokter kan ook jou nierfunksie nagaan.

ARLOZYB met voedsel en drank
Pomelo en pomelosap moet nie geneem word deur mense wat **ARLOZYB** gebruik nie. Dit is omdat pomelo en pomelosap kan lei tot 'n verhoging van die aktiewe bestanddeel amlodipien in die bloedvlakke, wat 'n onvoorspelbare toename in die bloeddrukverlagende effek van **ARLOZYB** kan veroorsaak.

Swangerskap en borsvoeding
Indien jy swanger is of borsvoed, dink dat jy moontlik swanger kan wees of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy **ARLOZYB** neem.
Die veiligheid van **ARLOZYB** in swanger en borsvoedende vrouens is nie vasgestel nie.
Jy moet nie **ARLOZYB** gebruik indien jy swanger is, probeer om swanger te word of jou baba borsvoed nie.
Indien jy 'n vrou van kinderbarende ouderdom is, moet jy seker maak dat jy 'n effektiewe voorbehoedmiddel gebruik.

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

Dit is nie altyd moontlik om te voorspel tot watter mate **ARLOZYB** met jou daaglikse aktiwiteite kan inmeng nie. Jy moet seker maak dat jy nie betrokke raak om 'n voertuig te bestuur of masjiene te gebruik, totdat jy bewus is van die mate waarin **ARLOZYB** jou affekteer nie.

3. Hoe om ARLOZYB te gebruik

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **ARLOZYB** presies soos jou dokter jou beveel het. Vra vir jou dokter of apteker indien jy onseker is.

Die gewone dosis van **ARLOZYB** is een tablet per dag.
- Dit is verkieslik om jou medisyne elke dag op dieselfde tyd te neem.
- Sluk die tablette met 'n glas water.
- Jy kan **ARLOZYB** met of sonder kos neem. Moet nie **ARLOZYB** saam met pomelo of pomelosap neem nie.

Afhangende van hoe jy op die behandeling reageer, kan jou dokter 'n hoër of laer dosering voorstel.

Moet nie die voorgeskrewe dosis oorskry nie.

ARLOZYB en ouer mense (ouderdom 65 jaar of ouer)
Jou dokter moet met omsigtigheid jou dosering verhoog.

Indien jy meer ARLOZYB neem as wat jy moet
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om ARLOZYB te neem
Moet nie 'n dubbele dosering neem om vir vergete individuele dosisse op te maak nie.

Indien jy ophou om ARLOZYB te gebruik
Indien jy jou behandeling met **ARLOZYB** stop, kan jou siekte vererger. Moet nie ophou om jou medisyne te neem nie, tensy jou dokter jou beveel om dit te doen.

4. Moontlike newe-effekte

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

Indien enige van die volgende simptome voorkom, staak die gebruik van **ARLOZYB** 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 om asem te haal;
- uitslag of jeuk;
- flou val.

Hierdie is almal baie ernstige newe-effekte. Indien jy dit het, het jy moontlik 'n ernstige allergiese reaksie teen **ARLOZYB** gehad. Jy mag dringende mediese aandag of hospitalisering nodig hê.

Vertel jou dokter onmiddellik of gaan na die ongevalle afdeling by jou naaste hospitaal indien jy enige van die volgende opmerk:
- sikliële gehyg, borskespyn, kortasem of moeilike asemhaling
- erge velreaksies insluitend intense veluitslag, netelroos, rooi word van die vel oor jou hele liggaam, erge jeuk, blase, afskilfering en swelling van die vel, inflammasie van die slymvliese (Stevens Johnson se sindroom, toksiese epidermale nekrolise) of ander allergiese reaksies
- ontsteekte pankreas, wat erge abdominale- en rugpyn kan veroorsaak wat gepaard gaan met 'n gevoel van baie slegvoel
- hartaanval, abnormale hartklop
- swelling van boonste lugweg

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

Sê vir jou dokter indien jy enige van die volgende waarneem:
Gereelde newe-effekte
- influensa (griep); verstopte neus, seer keel en ongemak wanneer jy skuk
- lae kaliumvlakke
- hoofpyn
- astenie (swakheid)
- duiseligheid
- maagpyn
- siek gevoel (naarheid)
- moegheid
- gesig swelling
- rooiheid en warm gevoel van die gesig en/of nek
- swelling in die liggaam wat veroorsaak word deur oortollige vloeistof. Dit affekteer dikwels die onderlyf, soos die bene, voete en enkel, maar dit kan enige plek voorkom.

Minder gereelde newe-effekte
- selfus verloor
- hoë kalsium-, suiker-, cholesterol- of uriensuurvlakke in die bloed
- lae natriumvlakke in die bloed
- voel angstig
- abnormale koördinasie
- lomerigheid, tinteling of gevoelloosheid van die hande of voete
- versteuring, en inkorting van sig
- gesuis in die ore, kop wat draai
- vinnige hartklop insluitend hartkloppings
- lae bloeddruk en ligh oofdigheid wanneer jy opstaan
- hoes, nies/loopneus wat veroorsaak word deur ontsteking van die slymvlies van die neus (rinitis)
- seer keel
- hardlywigheid, verandering in stoelgang,
- diarree, droë mond
- naarheid, braking, swak spysvertering
- oormatige sweet
- rooiheid van die vel
- veluitslag oor jou hele liggaam
- swelling van gewrigte
- rugpyn, pyn in gewrigte, spierspasme, spierkrampe
- gevoel van swaarheid
- passeer meer urine as normaalweg of voel 'n groter drang om te urineer
- onvermoë om 'n erreksie te kry of in stand te hou
- 'n lae witbloedselvlak in die bloed
- lae bloedplaatjietelling
- oortollige suiker in bloed (hiperglukemie)
- gemoedsveranderinge, depressie, verwering
- smaak versteurings, verlies van pynsensasie, abnormale sensasie, tipiese tinteling of prikking ("speldie en naaldie"), hoë vlak van spierstonus
- bewing, slapeloosheid, gedeeltelike of totale verlies van sensasie in 'n deel van jou liggaam.
- 'n ontsteking van die bloedvate wat veranderinge in die bloedvatwande veroorsaak
- swelling van die tandvleise
- abdominale opgeblasenheid (gastritis), verhoogde lewerensiemverhoging wat 'n uitwerking op sommige mediese toetse kan hê
- abnormale lewerfunksie, ontsteking van die lewer (hepatitis), geelwording van die vel (geelsug)
- hasrverlies
- velverkleuring
- velsensitiwiteit vir lig, pers kolle onder die vel, netelroos
- ongemak of vergroting van die borste in mans
- gebrek aan energie
- borskeapyn, voel onwel
- pyn
- gewigstoename of -afname

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, apteker of verpleegkundige. 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 **ARLOZYB**.

5. Hoe om ARLOZYB te bewaar

Bewaar by of benede 25 °C. Beskerm teen lig en vog.
Bewaar alle medisyne buite bereik van kinders.
Bewaar in die oorspronklike verpakking/houer.
Hou die stuipstroke in die buitenste karton totdat dit benodig word vir gebruik.
Moet nie in 'n badkamer bêre nie.
Moet nie na die vervaldatum wat aangebring is op die stuipstrook/etiket/karton/bottel gebruik nie.
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 ARLOZYB bevat
Die aktiewe bestanddele is amlodipienbesilaat en valsartaan.
Die ander bestanddele sluit in:
Tabletkern:
Mikrokristallyne sellulose, kruispovidoon, kolloïdale silikondioksied, magneslumstearaat.
Filmbedekking bevat:
Hipromellose, poliëtileenglikool 400, gesuiwerde talk, titaniumdioksied (C.I. no. 77891), geel ysteroksied (C.I. no. 77492) vir **ARLOZYB** 5/160 en 10/160 en rooi ysteroksied (C.I. no. 77491) –vir **ARLOZYB** TABLETTE 10/160.

Hoe ARLOZYB lyk en inhoud van die pak
Stulpverpakking: **ARLOZYB** 5/160 mg en 10/160 mg
Gewone 30 mikron aluminiumfoelie/6-8 gsm hittesëëllak as die dekmateriaal en Koue vorm laminaat, 25 µ OPA/45 µ aluminiumfoelie /60 µ PVC as die vormingsmateriaal, verpak in 'n voorafgedrukte eenheidskarton.
Verpakkings groottes 7's, 14's, 28's, 30's, 56's, 90's, 98's en 100's.

HDPE houer verpakking: **ARLOZYB** 5/160 mg and 10/160 mg
60 ml ronde, wit HDPE houer met 33 mm naskafwerking, wat 30 of 90 tablette bevat, toegemaak met wit kinderbestande polipropileen, met pulp en wit gedrukte hittesëëlvoering, 33 mm en verpak in 'n voorafgedrukte eenheidskarton.
Verpakkings groottes 30's en 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
01 Februarie 2022

Registrasienommer
ARLOZYB 5/160: 50/7.1.3/0313
ARLOZYB 10/160: 50/7.1.3/0314

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

280 mm

335 mm

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MACLEODS

Restricted Circulation

PACKAGING RESEARCH & DEVELOPMENT

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Exclusion of PI, text update, and dimension change.

1. Product: ARLOZYB 5/160, 10/160 (Amlodipine and Valsartan Tablets 5 mg +160 / 10 mg + 160 mg)	
2. Country: South Africa	3. Packaging component: Patient Information Leaflet
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 280 (W) mm
9. Design / Style: Booklet	10. Item code No.: PM03929602
11. Artwork has been made: Actual Size	12. Pharma code No.: 33335 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: PM03929601
15. Revision No: 01	16. A/W File name: Amlodipine and Valsartan SA Private Limited\02 Amlodipine and Valsartan PI & PL - PM03929602.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
16/11/22	Vanita Rajool	16/12/22	21-12-22	21/12/22	21/12/22

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 Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa	PM03929601	20/08/22	22/12/22
2) Exclusion of PI, text update, and dimension change.	PM03929602		

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