Front Side

370 mm

335 mm

ARLOZYB CO TABLETS
(film-coated tablet)
PM04273801

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S3

ARLOZYB CO TABLETS 5/160/12,5 mg
ARLOZYB CO TABLETS 5/160/25 mg
ARLOZYB CO TABLETS 10/160/12,5 mg
ARLOZYB CO TABLETS 10/160/25 mg
ARLOZYB CO TABLETS 10/320/25 mg
Amlodipine, Valsartan and Hydrochlorothiazide Tablets
Sugar free

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

1. What ARLOZYB CO TABLETS is and what it is used for

ARLOZYB CO TABLETS contain three substances called amlodipine, valsartan and hydrochlorothiazide.

All 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.
Hydrochlorothiazide belongs to a group of substances called "thiazide diuretics". Hydrochlorothiazide increases urine output, which also lowers blood pressure.

As a result of all three mechanisms, the blood vessels relax and blood pressure is lowered.

ARLOZYB CO TABLETS is used to treat high blood pressure in adult patients whose blood pressure is already controlled while taking amlodipine, valsartan and hydrochlorothiazide individually and who may benefit from taking one tablet containing all three substances.

2. What you need to know before you take ARLOZYB CO TABLETS

Do not take ARLOZYB CO TABLETS:
- If you are allergic to amlodipine, valsartan, hydrochlorothiazide or any of the other ingredients of this medicine, listed in section 6.
- If you have previously experienced swelling, particularly of the face and throat, while taking other medicines like **ARLOZYB CO TABLETS** (including angiotensin converting enzyme inhibitors/angiotensin receptor blockers). If you get these symptoms, stop taking **ARLOZYB CO TABLETS** and contact your doctor straight away. You should never take **ARLOZYB CO TABLETS** again.
- If you have recurrent episodes of severe swelling
- If you have severe liver impairment
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- if you have been diagnosed as suffering from a narrowing of your kidney artery or if you are suffering from severe kidney problems
- 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 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 are taking fluoroquinolones (antibiotics to treat infections)
- If you suffer from porphyria – a rare disease which causes the build up of chemicals in your body.
- If you are currently taking lithium
- If you are pregnant or breastfeeding.
- if you have Addison's disease – an uncommon disease that occurs when the body does not make enough of a hormone called cortisol.
- If you have severe kidney disease
- If you are under the age of 18
- If you have or had a form of skin or lip cancer called basal cell carcinoma or squamous cell carcinoma

Warnings and precautions
Talk to your doctor before taking **ARLOZYB CO TABLETS**
- if you are taking potassium-sparing medicines, potassium supplements, salt substitutes containing potassium or other medicines that increase the amount of potassium in your blood such as heparin. Your doctor may need to check the amount of potassium in your blood regularly,
- if you have low levels of potassium in your blood. Sometimes caused by kidney problems.
- if you are taking high doses of water tablets (diuretics).
- if you have severe heart disease.
- if you are suffering from heart failure or have experienced a heart attack. Follow your doctor's instruction for the starting dose carefully. Your doctor may also check your kidney function.
- if you suffer from a narrowing of the kidney artery.
- if you have recently received a new kidney.
- If you suffer from hyperaldosteronism. This is a disease in which your adrenal glands make too much of the hormone aldosterone. If this applies to you, the use of **ARLOZYB CO TABLETS** is not recommended.
- if you have liver or kidney disease.
- if you have ever experienced swelling of the tongue and face caused by an allergic reaction called angioedema when taking another medicine (including ACE inhibitors), tell your doctor. If these symptoms occur when you are taking **ARLOZYB CO TABLETS**, stop taking **ARLOZYB CO TABLETS** immediately and never take it again. See also section 4, "Possible side effects".
- if you have fever, rash and joint pain, which may be signs of systemic lupus erythematosus (SLE, a so-called autoimmune disease).
- if you have diabetes, gout, high levels of cholesterol or triglycerides in your blood.
- If you have had allergic reactions with the use of other blood pressure-lowering medicines of this class (angiotensin II receptor antagonists) or if you have allergy or asthma.
- if you experience a decrease in vision or eye pain. These could be symptoms of an increase of pressure in your eye and can happen within hours to a week of taking **ARLOZYB CO TABLETS**. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulphonamide allergy you can be at higher risk of developing this.
- if you are taking any of the following medicines used to treat high blood pressure:
- an ACE inhibitors (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
- aliskiren.
- if you have had skin cancer or if you develop an unexpected skin lesion during the treatment.
- Treatment with hydrochlorothiazide, particularly long term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking **ARLOZYB CO TABLETS.**

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. See also information under the heading "Do not take **ARLOZYB CO TABLETS**".
ARLOZYB CO TABLETS may cause increased sensitivity of the skin to sun. If this occurs you should stop your treatment and speak to your doctor. If it is necessary to continue your treatment, use a sunblock to protect your skin.

Use in children and adolescents
The use of **ARLOZYB CO TABLETS** in children and adolescents (below the age of 18 years) is not recommended.

Other medicines and ARLOZYB CO TABLETS
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
The effect of the treatment can be influenced if **ARLOZYB CO TABLETS** is taken together with certain other medicines. It may be necessary to change the dose, to take other precautions, or in some cases to stop taking one of the medicines. This especially applies to the following medicines:
- lithium, a medicine used to treat some types of psychiatric diseases.
  Taking lithium with **ARLOZYB CO TABLETS** may lead to dangerously increased levels of lithium.
- medicines or substances that may increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin.
- medicines that may reduce the amount of potassium in your blood, such as diuretics (water tablets), corticosteroids, laxatives, carbenoxolone, amphotericin or penicillin G.
- some antibiotics (rifamycin group), a medicine used to protect against transplant rejection (ciclosporin) or an antiretroviral medicine used to treat HIV/AIDS infection (ritonavir). These medicines may increase the effect of **ARLOZYB CO TABLETS.**
- medicines that may induce "torsades de pointes" (irregular heart beat), such as antidysrhythmics (medicines used to treat heart problems) and some antipsychotics.
- medicines that may reduce the amount of sodium in your blood, such as antidepressants, antipsychotics, antiepileptics.
- medicines for the treatment of gout, such as allopurinol, probenecid, sulfinpyrazone. The dose of these medicines may have to be adjusted.
- therapeutic vitamin D and calcium supplements, as they may increase the amount of calcium in your blood.
- medicines for the treatment of diabetes (oral medicines such as metformin or insulins). The doses of these medicines may have to be adjusted. Taking metformin with **ARLOZYB CO TABLETS** may increase the chance of serious side effects.
- other medicines to lower your blood pressure including methyldopa, ACE inhibitors (such as enalapril, lisinopril, etc.) or aliskiren (see also information under the headings "Do not take **ARLOZYB CO TABLETS**" and "Warnings and precautions"). These may increase the blood pressure lowering effect of **ARLOZYB CO TABLETS.**
- medicines to increase blood pressure, such as noradrenaline or adrenaline.
- digoxin or other digitalis glycosides (medicines used to treat heart problems) as the effect of these medicines may be increased.
- medicines that may increase blood sugar levels, such as diazoxide or beta blockers, as their effect may be increased.
- cytotoxic medicines (used to treat cancer), such as methotrexate or cyclophosphamide, as their effect may be increased.
- pain killers such as non-steroidal anti-inflammatory medicines (NSAIDs), including selective cyclo-oxygenase-2 inhibitors (Cox-2 inhibitors) and acetylsalicylic acid > 3 g. These medicines may increase potassium levels and cause kidney problems when taken with **ARLOZYB CO TABLETS**
- muscle relaxing medicines, such as tubocurarine, as its effect may be increased.
- anti-cholinergic medicines (medicines used to treat a variety of disorders such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, Parkinson's disease and as an aid to anaesthesia). These medicines may increase the effect of **ARLOZYB CO TABLETS.**
- amantadine (medicine used to treat Parkinson's disease and also used to treat or prevent certain illnesses caused by viruses), as it may cause increased side effects.
- cholestyramine and colestipol (medicines used mainly to treat high levels of lipids in the blood). It may decrease the effect of **ARLOZYB CO TABLETS.**
- ciclosporin, a medicine used for organ transplant to avoid organ rejection, it may increase the effect of **ARLOZYB CO TABLETS.**
- alcohol, sleeping pills and anaesthetics (medicines with sleeping or painkilling effect used for example during surgery), may increase the blood pressure lowering effect of **ARLOZYB CO TABLETS.**
- Iodine contrast media (agents used for imaging examinations), may increase the risk of kidney problems.
- simvastatin (a medicine used to control high cholesterol levels) used with **ARLOZYB CO TABLETS,** may increase the effect of simvastatin;
- anticonvulsant agents (e.g. carbamazepine, phenobarbital, phenytoin, fosphenytoin, primidone) may decrease the sodium levels in the blood.

ARLOZYB CO TABLETS with food and drink:
Avoid drinking alcohol as alcohol may make your blood pressure fall more and/or increase the risk of you becoming dizzy or feeling faint.
Grapefruit and grapefruit juice should not be consumed by people who are taking **ARLOZYB CO TABLETS.** 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 CO TABLETS.**

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **ARLOZYB CO TABLETS.**

Do not take **ARLOZYB CO TABLETS** if you are pregnant, are considering becoming pregnant or are breastfeeding.

If you are a woman of childbearing age, you must use effective contraception.

Driving and using machines
Before you drive a vehicle, use tools or operate machines or carry out other activities that require concentration, make sure you know how **ARLOZYB CO TABLETS** affects you. **ARLOZYB CO TABLETS** may occasionally cause dizziness and affect the ability to concentrate.

3. How to take ARLOZYB CO TABLETS

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

Always take **ARLOZYB CO TABLETS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose is one tablet per day.
You can take **ARLOZYB CO TABLETS** with or without food.
Do not take **ARLOZYB CO TABLETS** with grapefruit or grapefruit juice.

If you have the impression that the effect of **ARLOZYB CO TABLETS** is too strong or too weak, talk to your doctor or pharmacist.

If you take more ARLOZYB CO TABLETS than you should

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

If you forget to take ARLOZYB CO TABLETS
It is important to take your **ARLOZYB CO TABLETS** regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take two doses at the same time, to make up for a missed dose.

If you stop taking ARLOZYB CO TABLETS
If **ARLOZYB CO TABLETS** is stopped earlier than your doctor has prescribed, your symptoms of may return or worsen. Always take **ARLOZYB CO TABLETS** for as long as your doctor has prescribed.

4. Possible side effects

ARLOZYB CO TABLETS can have side effects.
Not all side effects reported for **ARLOZYB CO TABLETS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **ARLOZYB CO TABLETS**, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking **ARLOZYB CO TABLETS** 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 reaction to **ARLOZYB CO 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:
- severe skin disease that causes rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (toxic epidermal necrolysis),
- decrease in vision or pain in your eyes due to high pressure (possible signs of acute angle closure glaucoma),
- fever, sore throat, more frequent infections (agranulocytosis),
- sudden wheeziness, chest pain, shortness of breath or difficulty in breathing
- inflamed pancreas, which may cause severe abdominal and back pain accompanied with feeling of being very unwell
- heart attack, abnormal heartbeat
- upper airway swelling
- If you feel light headed, dizzy or weak due to very low blood pressure
- if you feel dizzy when you suddenly stand up from sitting or lying down.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent
- itchy rash and other types of rash,
- reduced appetite,
- mild nausea and vomiting,
- dizziness, fainting on standing up,
- inability to achieve or maintain erection
- headache
- Feeling sleepy
- palpitations (feeling like your heart is racing, pounding)
- 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
- Frequent urination
- low blood pressure

Less frequent:
- Cough, difficulty in breathing, sneezing/ runny nose caused by inflammation of the lining of the nose (rhinitis)
- light-headedness,
- dehydration (with symptoms of thirst, dry mouth and tongue, infrequent urination, dark colored urine, dry skin),
- muscle pain,
- tiredness,
- Drowsiness, tingling or numbness (usually in hands or feet) or loss of sensation
- blurred vision, seeing double
- noises (e.g. hissing, buzzing) in ears,
- Dizziness, abnormal co-ordination
- Stiffness or difficulty in movement
- Changes in taste
- Diarrhoea
- joint pain or swelling,
- spinning sensation,
- swelling and blistering of the skin (due to increased sensitivity to sun),
- worsening of diabetic metabolic state (feeling extremely thirsty, frequent urination, lethargy)
- constipation, diarrhoea, discomfort of the stomach or bowels, liver disorders which can occur together with yellow skin and eyes,
- Irregular heartbeat,
- sleep disturbances,
- sad mood (depression),
- low level of blood platelets (sometimes with bleeding or bruising underneath the skin),
- inflammation of blood vessels with symptoms such as rash, purplish-red spots, fever (vasculitis),
- facial rash, joint pain muscle disorder, fever (lupus erythematosus),
- severe upper stomach pain (pancreatitis),
- difficulty breathing with fever, wheezing, breathlessness (respiratory distress including pneumonitis and pulmonary oedema),
- pale skin, tiredness, breathlessness, dark urine (haemolytic anaemia),
- fever, sore throat or mouth ulcers due to infections (leucopenia,)
- confusion, tiredness, muscle twitching and spasm, rapid breathing (hypochloraemic alkalosis),
- Excessive sweating
- Swelling of the gums
- abdominal bloating (gastritis)
- 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
- weight increase or decrease
- If you notice any lump or patch on the skin that is not healing.
- Asthenia (weakness)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist. Should your general health worsen or if you experience any untoward effects while taking **ARLOZYB CO TABLETS**, please consult your healthcare provider for advice.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Adverse drug reaction and quality reporting form, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8
https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality problem reporting form.
By reporting side effects, you can help provide more information on the safety of **ARLOZYB CO TABLETS.**

5. How to store ARLOZYB CO TABLETS

For Blister Pack: Store at or below 30 °C.
For HDPE Container Pack: Store at or below 25 °C.
Protect from light and moisture.
KEEP OUT OF THE REACH OF CHILDREN.
Store in the original package / container.
Keep the blisters in the carton until required for use.
Keep the HDPE container tightly closed.
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 pack and other information

What ARLOZYB CO TABLETS contains
The active ingredients are amlodipine, valsartan and hydrochlorothiazide.
Sugar free
The other ingredients are:
Tablet core
Microcrystalline cellulose, crospovidone, colloidal silicon dioxide and magnesium stearate

Coating material contains
ARLOZYB CO TABLETS 5/160/12,5 mg
HPMC 2910/Hypromellose 6 cPs, polyethylene glycol 4000, talc and Titanium dioxide.

ARLOZYB CO TABLETS 5/160/25 mg
HPMC 2910/Hypromellose 6 cPs, polyethylene glycol 4000, talc, Titanium dioxide and Iron oxide yellow.

ARLOZYB CO TABLETS 10/160/12,5 mg
HPMC 2910/Hypromellose 6 cPs, polyethylene glycol 4000, talc, Titanium dioxide, Iron oxide yellow and Iron oxide red.

ARLOZYB CO TABLETS 10/160/25 mg and 10/320/25 mg
HPMC 2910/Hypromellose 6 cPs, polyethylene glycol 4000, talc and Iron oxide yellow.

What ARLOZYB CO TABLETS looks like and contents of the pack
ARLOZYB CO TABLETS 5/160/12,5 mg: White, oval shaped, biconvex, film coated tablets debossed with "T23" on one side and plain on other side.
ARLOZYB CO TABLETS 5/160/25 mg: Yellow, oval shaped, biconvex, film coated tablets debossed with "T25" on one side and plain on other side.
ARLOZYB CO TABLETS 10/160/12,5 mg: Pale yellow, oval shaped, biconvex, film coated tablets debossed with "C96" on one side and plain on other side.
ARLOZYB CO TABLETS 10/160/25 mg: Brown yellow, oval shaped, biconvex, film coated tablets debossed with "C97" on one side and plain on other side.
ARLOZYB CO TABLETS 10/320/25 mg: Brown yellow, oval shaped, biconvex, film coated tablets debossed with "T98" on one side and plain on other side.

Contents of the pack:
1) Blister Pack:
Tablets are packed in blisters of cold form laminate 25 µm OPA / 45 µm aluminium foil / 60 µm PVC as the forming material and 30 µ aluminium plain foil/ 6-8 gsm heat seal lacquer as the lidding material, packed in a pre-printed carton.
Pack size include 7, 10, 14, 28, 56 or 98 tablets.

2) HDPE Container
30 tablets are packed in round shaped, white 60 ml HDPE container with 33-400 neck finish which are closed with 33 mm child resistant closure with pulp and heat seal white printed liner.
Not all pack sizes may be marketed.

Holder of Certificate of Registration
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Ground Floor, Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock Ext 12
Alberton
Gauteng

This leaflet was last revised in
05 December 2023

Registration numbers
ARLOZYB CO TABLETS 5/160/12,5 mg: 56/7.1.3/0560
ARLOZYB CO TABLETS 5/160/25 mg: 56/7.1.3/0561
ARLOZYB CO TABLETS 10/160/12,5 mg: 56/7.1.3/0562
ARLOZYB CO TABLETS 10/160/25 mg: 56/7.1.3/0563
ARLOZYB CO TABLETS 10/320/25 mg: 56/7.1.3/0564

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169

Back Side

370 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S3

ARLOZYB CO TABLETS 5/160/12,5 mg
ARLOZYB CO TABLETS 5/160/25 mg
ARLOZYB CO TABLETS 10/160/12,5 mg
ARLOZYB CO TABLETS 10/160/25 mg
ARLOZYB CO TABLETS 10/320/25 mg
Amlodipien, Valsartan en Hidrochloortiasied Tablette
Sulkervry

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

1. Wat ARLOZYB CO TABLETS is en waarvoor dit gebruik word

ARLOZYB CO TABLETS bevat drie stowwe naamlik amlodipien, valsartan en hidrochloortiasied.

Almal van hierdie stowwe help om hoë bloeddruk te beheer
Amlodipien behoort aan 'n groep stowwe wat "kalsiumkanaalblokkeerders" genoem word. Amlodipien verhoed dat kalsium in die bloedvatwand inbeweeg, wat keer dat die bloedvate saamtrek.

Valsartan behoort aan 'n groep stowwe wat "angiotensien II reseptorantagoniste" genoem word. Angiotensien II word deur die liggaam geproduseer en laat die bloedvate saamtrek om sodoende die bloeddruk te verhoog. Valsartan werk deur die effek van angiotensien II te blokkeer.

Hidrochloortiasied behoort aan 'n groep stowwe wat "tiasieddiuretika" genoem word. Hidrochloortiasied verhoog urienproduksie, wat ook bloeddruk verlaag.

As 'n resultaat van al drie meganismes, ontspan die bloedvate en verlaag die bloeddruk.

ARLOZYB CO TABLETS word gebruik om hoë bloeddruk te behandel in volwasse pasiente, wie se bloeddruk reeds beheer word terwyl hulle amlodipien, valsartan en hidrochloortiasied individueel neem, en wie moontlik kan baat deur net een tablet te neem, wat al drie stowwe bevat.

2. Wat jy behoort te weet voordat jy ARLOZYB CO TABLETS neem

Moet nie ARLOZYB CO TABLETS neem nie:
- Indien jy allergies is vir amlodipien, valsartan, hidrochloortiasied of enige van die ander bestanddele van hierdie medisyne, gelys in afdeling 6.
- Indien jy voorheen swelling ervaar het, veral van die gesig en keel, terwyl jy ander medisyne soos **ARLOZYB CO TABLETS** (insluitend angiotensien omskakelende ensiem inhibeerders/ angiotensien reseptor blokkeerders) geneem het. Indien jy hierdie simptome kry, hou op om **ARLOZYB CO TABLETS** te neem en kontak onmiddellik jou dokter. Jy moet nooit weer **ARLOZYB CO TABLETS** neem nie.
- Indien jy herhalende episodes van erge swelling het
- Indien jy ernstige lewerinkorting het
- Indien jy diabetes of ingekorte nierfunksie het en jy behandel word met 'n bloeddruk verlagende middel wat aliskiren bevat.
- Indien jy gediagnoseer is as iemand wat ly aan 'n vermouting van jou hierstagaar of indien jy aan ernstige nierprobleme ly
- Jou dokter het gediagnoseer dat jy ly aan 'n vermouting van kleppe in jou hart (genoem aorta- of mitraal stenose), of abnormaal verhoogde dikte van jou hartspier met vermouting (genoem obstruktiewe hipertroffese kardiomiopatie)
- Indien jy ander medisyne of stowwe gebruik wat die kaliumvlakke in jou bloed verhoog (soos sekere tipes diuretika, kaliumaanvullings, ens.)
- Indien jy fluorokinolone gebruik (antibiotika om infeksies te behandel)
- Indien jy aan porfirie ly – 'n seldsame siekte wat die opbou van chemikalieë in jou liggaam veroorsaak.
- Indien jy tans litium neem
- Indien jy swanger is of borsvoed.
- Indien jy Addison se siekte het - 'n ongewone siekte wat voorkom wanneer die liggaam nie genoeg van 'n hormoon, naamlik kortisol, maak nie.
- Indien jy ernstige niersiekte het
- Indien jy onder die ouderdom van 18 is
- Indien jy 'n vorm van vel- of lipkanker naamlik basaalselkanker of skwameuse sel kanker het, of gehad het

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter voordat jy **ARLOZYB CO TABLETS** neem
- Indien jy kaliumsparende medisyne, kaliumaanvullings, soutvervangers wat kalium bevat of ander medisyne gebruik wat die hoeveelheid kalium in jou bloed verhoog, soos heparien. Jou dokter sal moontlik gereeld die hoeveelheid kalium in jou bloed moet kontroleer.
- Indien jy lae vlakke van kalium in jou bloed het. Soms veroorsaak deur nierprobleme.
- Indien jy hoë dosisse van watertablette (diuretika) neem.
- Indien jy ernstige hartsiekte het.
- Indien jy aan hartversaking ly of 'n hartaanval ervaar het. Volg noukeurig jou dokter se instruksies vir die aanvangsdosis. Jou dokter kan ook jou nierfunksie nagaan.
- Indien jy aan 'n vermouting van die nierslagaar ly.
- Indien jy onlangs 'n nuwe nier ontvang het.
- Indien jy aan hiperaldosteronisme ly. Dit is 'n siekte waarin jou byniere te veel van die hormoon aldosteroon vervaardig. Indien dit op jou van toepassing is, word die gebruik van **ARLOZYB CO TABLETS** nie aanbeveel nie.
- Indien jy 'n lewer- of niersiekte het.
- Vertel jou dokter indien jy al ooit swelling van die tong en gesig ervaar het wat veroorsaak is deur 'n allergiese reaksie, bekend as angioödeem, wanneer jy 'n ander medisyne gebruik het (insluitend ACE-inhibeerders). Indien hierdie simptome voorkom wanneer jy **ARLOZYB CO TABLETS** neem, hou onmiddellik op om **ARLOZYB CO TABLETS** te neem en moet dit nooit weer neem nie. Sien ook afdeling 4, "Moontlike newe-effekte".
- Indien jy koors, uitslag en gewrigspyn het, wat moontlik tekens van sistemiese lupus erythematosus (SLE, 'n siogenaamde outo-immuun siekte) kan wees.
- Indien jy diabetes, jig, hoë vlakke van cholesterol of triglisiede in jou bloed het.
- Indien jy allergiese reaksies gehad het met die gebruik van ander bloeddrukverlagende medisyne van hierdie klas (angiotensien II reseptorantagoniste) of indien jy allergie of asma het.
- Indien jy 'n afname in visie of oogpyn ervaar. Dit kan simptome wees van 'n verhoging in druk in jou oog en kan binne ure tot 'n week na die neem van **ARLOZYB CO TABLETS** gebeur. Dit kan lei tot permanente sigverlies, indien dit nie behandel word nie. Indien jy vroeër 'n penisillien- of sulfonamied allergie gehad het, kan jy 'n groter risiko hê om dit te ontwikkel.
- Indien jy enige van die volgende medisyne neem wat gebruik word om hoë bloeddruk te behandel:
- 'n ACE inhibeerder (byvoorbeeld enatapril, lisinopril, ramipril), veral indien jy diabetes verwante nierprobleme het.
- aliskiren.
- Indien jy voorheen velkanker gehad het of as jy 'n onverwagse velletjel tydens die behandeling ontwikkel.
- Behandeling met hidrochloortiasied, veral langtermyn gebruik met hoë dosisse, kan die risiko van sommige tipes vel- en lipkanker (nie-melanoom velkanker) verhoog. Beskerm jou vel teen sonblootstelling en UV-strale terwyl jy **ARLOZYB CO TABLETS** gebruik.

Kontak jou dokter om jou behandeling te hersvalueer indien jy met AOE inhibeerders/Angiotensien reseptor blokkeerders saam met 'n fluorokinokoon antibiotikum behandel word. Jou dokter kan jou nierfunksie, bloeddruk en die hoeveelheid elektroliete (bv. kalium) in jou bloed met gereelde tussenposos nagaan. Sien ook inligting onder die opskrif "Moet nie **ARLOZYB CO TABLETS** neem nie".

ARLOZYB CO TABLETS kan verhoogde sensitiwiteit van die vel vir son veroorsaak. Indien dit gebeur, moet jy jou behandeling staak en met jou dokter praat. Indien dit nodig is om jou behandeling voort te sit, gebruik 'n sonskerm om jou vel te beskerm.

Gebruik in kinders en adolessente
Die gebruik van **ARLOZYB CO TABLETS** in kinders en adolessente (onder die ouderdom van 18 jaar) word nie aanbeveel nie.

Ander medisyne en ARLOZYB CO TABLETS
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Die effek van die behandeling kan beïnvloed word indien **ARLOZYB CO TABLETS** saam met sekere ander medisyne geneem word. Dit mag nodig wees om die dosis te verander, om ander voorsorgmaatreëls te tref, of in sommige gevalle om op te hou om een van die medisyne te neem. Dit geld veral vir die volgende medisyne:
- litium. 'n medisyne wat gebruik word om sekere soorte psigiatriese siektes te behandel.

Die neem van litium saam met **ARLOZYB CO TABLETS** kan lei tot gevaarlike verhoogde vlakke van litium.
- medisyne of stowwe wat die hoeveelheid kalium in jou bloed kan verhoog. Dit sluit in kaliumaanvullings of soutvervangers wat kalium bevat, kaliumbesparende medisyne en heparien.
- medisyne wat die hoeveelheid kalium in jou bloed kan verminder, soos diuretika (watertablette), kortikosteroïede, lakseermiddels, karbenoksoloon, amfoterisien of penisillien G.
- sommige antibiotika (rifamisiengroep), 'n medisyne wat gebruik word om teen verwerping van 'n oorplanting te beskerm (siklosporien) of 'n antiretrovirale medisyne wat gebruik word om MIV/VIGS infeksie te behandel (ritonavir). Hierdie medisyne kan die effek van **ARLOZYB CO TABLETS** verhoog.
- medisyne wat "*torsades de pointes*" (onreëlmatige hartklop) kan veroorsaak, soos antidisritmikum (medisyne wat gebruik word om hartprobleme te behandel) en sommige antipsigotikum.
- medisyne wat die hoeveelheid natrium in jou bloed kan verminder, soos antidepressante, antipsigotikum, anti-epileptikum.
- medisyne vir die behandeling van jig, soos allopurinol, probenesied, sulfinpirasoon. Die dosis van hierdie medisyne moet heel moontlik aangepas word.
- terapeutiese vitamien D en kalsiumaanvullings, aangesien dit die hoeveelheid kalsium in jou bloed kan verhoog.
- medisyne vir die behandeling van diabetes (orale medisyne soos metformien of insuliene). Die dosisse van hierdie medisyne moet heel moontlik aangepas word. Die neem van metformien saam met **ARLOZYB CO TABLETS** kan die kans op ernstige newe-effekte verhoog.
- ander medisyne om jou bloeddruk te verlaag, insluitend metieldopa, AOE inhibeerders (soos enalapril, lisinopril, ens.) of allskiren (sien ook inligting onder die opskrifte "Moet nie **ARLOZYB CO TABLETS** neem nie" en "Waarskuwings en voorsorgmaatreëls"). Dit kan die bloeddrukverlagende effek van **ARLOZYB CO TABLETS** verhoog.
- medisyne om bloeddruk te verhoog, soos noradrenalien of adrenalien.
- digoksien of ander digitalis-glikosiede (medisyne wat gebruik word vir die behandeling van hartprobleme) aangesien die effek van hierdie medisyne verhoog kan word.
- medisyne wat bloedsuikervlakke kan verhoog, soos diasoksied of betablokkers, aangesien die effek van hierdie medisyne verhoog kan word.
- sitotoksiese medisyne (wat gebruik word om kanker te behandel), soos metotreksaat of siklofosfamied, aangesien die effek van hierdie medisyne verhoog kan word.
- pynstillers soos nie-steroïdale anti-inflammatoriese medisyne (NSAIMs), insluitend selektiewe siklo-oksigenase-2 inhibeerders (Cox-2 inhibeerders) en asetielsalisielsuur > 3 g. Hierdie medisyne kan kaliumvlakke verhoog en nierprobleme veroorsaak wanneer dit saam met **ARLOZYB CO TABLETS** geneem word
- spierverslappende medisyne, soos tubokurarien, aangesien die effek van hierdie medisyne verhoog kan word.
- anti-cholinergiese medisyne (medisyne wat gebruik word vir die behandeling van 'n verskeidenheid van afwykings soos gastrointestinale krampe, urinêre blaas spasmes, asma, bewegingsiekte, spierspasmas, Parkinson se siekte en as 'n hulpmiddel vir narkose). Hierdie medisyne kan die effek van **ARLOZYB CO TABLETS** verhoog.
- amantadien (medisyne wat gebruik word om Parkinson se siekte te behandel en ook gebruik word om sekere siektes wat deur virusse veroorsaak word te behandel of te voorkom), aangesien dit verhoogde newe-effekte kan veroorsaak.
- cholestiramien en kolestipol (medisyne wat hoofsaaklik gebruik word om hoë vlakke van lipiede in die bloed te behandel). Dit kan die effek van **ARLOZYB CO TABLETS** laat afneem.
- siklosporien, 'n medisyne wat gebruik word vir orgaanoorplanting om orgaanverwerping te verhoed, dit kan die effek van **ARLOZYB CO TABLETS** verhoog.
- alkohol, slaappille en vertoewings middels (medisyne met slaap- of pynstillende effek wat byvoorbeeld tydens chirurgie gebruik word), kan die bloeddrukverlagende effek van **ARLOZYB CO TABLETS** verhoog.
- Jodium kontrasmedium (middels wat gebruik word vir beeldondersoeke), kan die risiko van nierprobleme verhoog.
- simvastatien ('n medisyne wat gebruik word om hoë cholesterolvlakke te beheer) as dit saam met **ARLOZYB CO TABLETS** gebruik word, kan die effek van simvastatien verhoog;
- antikonvulsiewe middels (bv. karbamasepien, fenobarbiloon, fenitoïen, fosfenitoïen, primidoon) kan die natriumvlakke in die bloed verlaag.

ARLOZYB CO TABLETS met voedsel en drank:
Vermy die drink van alkohol aangesien alkohol jou bloeddruk meer kan laat daal en/of die risiko verhoog dat jy duiselig word of flou voel.
Pomelo en pomelosap moet nie verbruik word deur mense wat **ARLOZYB CO TABLETS** neem nie. Dit is omdat pomelo en pomelosap kan lei tot 'n toename in die bloedvlakke van die aktiewe stof amlodipien, wat 'n onvoorspelbare verhoging in die bloeddrukverlagende effek van **ARLOZYB CO TABLETS** kan veroorsaak.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy **ARLOZYB CO TABLETS** neem.

Moet nie **ARLOZYB CO TABLETS** neem indien jy swanger is, of oorweeg om swanger te raak, of borsvoed nie.

Indien jy 'n vrou van kinderbarende ouderdom is, moet jy effektiewe voorbehoeding gebruik.

Bestuur en gebruik van masjinerie
Voordat jy 'n voertuig bestuur, gereedskap gebruik of masjiene beheer of ander aktiwiteite uitvoer wat konsentrasie vereis, maak seker dat jy weet hoe **ARLOZYB CO TABLETS** jou affekteer. **ARLOZYB CO TABLETS** kan soms duiseligheid veroorsaak en die vermoë om te konsentreer beïnvloed.

3. Hoe om ARLOZYB CO TABLETS te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem altyd **ARLOZYB CO TABLETS** presies soos jou dokter jou voorgeskryf het. Jy moet jou dokter of apteker raadpleeg indien jy nie seker is nie.

Die aanbevole dosis is een tablet per dag.
Jy kan **ARLOZYB CO TABLETS** met of sonder kos neem.
Moet nie **ARLOZYB CO TABLETS** saam met pomelo of pomelosap neem nie.

Indien jy die indruk kry dat die effek van **ARLOZYB CO TABLETS** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer ARLOZYB CO TABLETS 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 CO TABLETS te neem
Dit is belangrik om jou **ARLOZYB CO TABLETS** gereeld op dieselfde tyd elke dag te neem. Indien jy vergeet om 'n dosis te neem, neem dit so gou as wat jy daarvan onthou, tensy dit tyd is vir jou volgende dosis. Moet nie twee dosisse op dieselfde tyd neem, om op te maak vir die dosis wat jy vergeet het nie.

Indien jy ophou om ARLOZYB CO TABLETS te neem
Indien **ARLOZYB CO TABLETS** vroeër gestaak word as wat jou dokter voorgeskryf het, kan jou simptome terugkeer of vererger. Neem altyd **ARLOZYB CO TABLETS** vir so lank as wat jou dokter dit voorgeskryf het.

4. Moontlike newe-effekte

ARLOZYB CO TABLETS kan newe-effekte hê.
Nie al die newe-effekte wat vir **ARLOZYB CO TABLETS** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid agteruitgaan, of as jy enige ongewenste effekte ervaar terwyl jy **ARLOZYB CO TABLETS** neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.
Indien enige van die volgende gebeur, hou op om **ARLOZYB CO TABLETS** te neem en vertel onmiddellik jou dokter of gaan na die ongevalle-afdeling van jou naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal,
- uitslag of jeuk.
- Floute

Hierdie is almal baie ernstige newe-effekte. Indien jy dit kry, het jy moontlik 'n ernstige reaksie op **ARLOZYB CO TABLETS** gehad. Jy moet dalk dringende mediese hulp of hospitalisasie kry.

Vertel onmiddellik vir jou dokter of gaan na die ongevalle-afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:
- ernstige velsiekte wat uitslag, rooi vel, blaasvorming van die lippe, oë of mond, afdop van vel, koors veroorsaak (toksiese epidermale nekrolise),
- afname in visie of pyn in jou oë as gevolg van hoë druk (moontlike tekens van akute sluitingshoek gloukoom),
- koors, seer keel, meer gereelde infeksies (agranulositose).
- skielike gehyg, borskaspyn, kort van asem of probleme om asem te haal
- ontsteekte pankreas, wat erge abdominale- en rugpyn kan veroorsaak, gepaardgaande met 'n gevoel van nie wel voel nie
- hartaanval, abnormale hartklop
- swelling van die boonste lugweg
- indien jy ligkoofdig, duiselig of swak voel as gevolg van bale lae bloeddruk
- indien jy duiselig voel wanneer jy skielik opstaan vanuit 'n sit- of lê posisie.

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

Vertel jou dokter indien jy enige van die volgende opmerk:
Gereeld
- jeukerige uitslag en ander soorte uitslag.
- verminderde eetlus,
- ligte naarheid en braking,
- duiseligheid, floute wanneer jy opstaan,
- onvermoë om ereksie te bereik of te handhaaf
- hoofpyn
- slaperig voel
- palpitasies (voel of jou hart jaag, hartkloppings)
- maagpyn
- siek voel (naarheid)
- moegheid
- swelling van gesig
- rooiheid en warm gevoel van die gesig en/of nek
- swelling in die liggaam wat veroorsaak word deur oortollige vloeistof. Dit tas dikwels die onderlyf, soos die bene, voete en enkels aan, maar dit kan oral voorkom
- Gereelde urinering
- lae bloeddruk

Minder gereeld:
- Hoes, moeilike asemhaling, nies/floopneus wat veroorsaak word deur ontsteking van die slymvlies van die neus (rinitis)
- lighoofdigheid,
- dehidrasie (met simptome van dors, droë mond en tong, ongereelde urinering, donkerdeurige uriene, droë vel),
- spierpyn,
- moegheid,
- Lomerigheid, tinteling of gevoelloosheid (gewoonlik in hande of voete) of verlies van sensasie
- dowwe visie, sien dubbeld
- geluide (bv. sis, suising) in ore.
- Duiseligheid, abnormale koördinasie
- Styfheid of probleme met beweging
- Veranderinge in smaak
- Diarree
- gewrigspyn of swelling.
- drasi sensasie,
- swelling en blase op die vel (as gevolg van verhoogde sensitiwiteit vir son),
- verergering van diabetiese metaboliese toestand (voel uitermatig dors, gereelde urinering, duiseligheid)
- hardlywigheid, diarree, ongemak van die maag of ingewande, lewerafwykings wat saam met geel vel en oë kan voorkom,
- onreëlmatige hartklop,
- slaapverstoorings,
- hartseer bui (depressie),
- lae vlak van bloedplaatjies (soms met bloeding of kneusing onder die vel),
- ontsteking van bloedvate met simptome soos uitslag, persrooi kolle, koors (vaskulitis),
- gesiguitslag, gewrigspyn, spierafwyking, koors (lupus erythematosus),
- erge boonste maagpyn (perikreatitis),
- moeilike asemhaling met koors, hyg, uitasem (respiratoriese nood insluitend longontsteking en pulmonêre edeem),
- bleek vel, moegheid, kort van asem, donker uriene (hemolitiese anemie),
- koors, seer keel of mondsere as gevolg van infeksies (leukopenie),
- verwarring, moegheid, spiertrekkings en spasme, vinnige asemhaling (hipochloremiese alkalose),
- Oormatige sweet
- Swelling van die tandvlees
- abdominale opgeblasenheid (gastritis)
- abnormale lewerfunksie, ontsteking van die lewer (hepatitis), vergeling van die vel (geelsug)
- haarverlies
- verkleuring van vel
- vel sensitiwiteit vir lig, pers kolle onder die vel, gebulte
- ongemak of vergroting van die borste in mans
- gewigstoename of -afname
- Indien jy enige knop of area op die vel sien wat nie genees nie.
- Astenia (swakheid)

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, stel asseblief jou dokter of apteker in kennis.
Indien jou algemene gesondheid agteruitgaan of as jy enige ongewenste effekte ervaar terwyl jy **ARLOZYB CO TABLETS** neem, raadpleeg Indiensebliet jou gesondheidsorgverskaffer vir advies.

Rapportering van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die "Adverse drug reaction and quality reporting form", wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8 https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality probleme rapporterings vorm. Deur newe-effekte aan te meld, kan jy help om meer inligting te verskaf oor die veiligheid van **ARLOZYB CO TABLETS.**

5. Hoe om ARLOZYB CO TABLETS te stoor

Vir stulpverpakking: Berg by of benede 30 °C.
Vir HDPE houer verpakking: Berg by of benede 25 °C.
Beskerm teen ligin vog.
HOU BUITE DIE BEREIK VAN KINDERS.
Berg in die oorspronklike verpakking/houer.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Hou die HDPE houer dig toe.
Moet nie in 'n badkamer stoor nie.
Moet nie gebruik na die vervaldatum wat aangedui word op die stulpstrook/etiket /karton/bottel nie. Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv, toilette) weggooi nie.

6. Inhoud van pakkie en ander inligting

Wat ARLOZYB CO TABLETS bevat
Die aktiewe bestanddele is amlodipien, valsartan en hidrochloortiasied.
Sulkervry
Die ander bestanddele is:
Tabletkern
Mikrokristalline sellulose, kruispovidoon, kolloïdale silikondioksied en magnesiumstearaat

Bedekkingsmateriaal bevat
ARLOZYB CO TABLETS 5/160/12,5 mg
HPMC 2910/Hipromellose 6 cPs, poliëtileenglikol 4 000, talk en titaandioksied.

ARLOZYB CO TABLETS 5/160/25 mg
HPMC 2910/Hipromellose 6 cPs, poliëtileenglikol 4 000, talk, titaandioksied en geel ysteroksied.

ARLOZYB CO TABLETS 10/160/12,5 mg
HPMC 2910/Hipromellose 6 cPs, poliëtileenglikol 4 000, talk, titaandioksied, geel ysteroksied en rooi ysteroksied.

ARLOZYB CO TABLETS 10/160/25 mg en 10/320/25 mg
HPMC 2910/Hipromellose 6 cPs, poliëtileenglikol 4 000, talk en geel ysteroksied.

Hoe ARLOZYB CO TABLETS lyk en die inhoud van die verpakking
ARLOZYB CO TABLETS 5/160/12,5 mg: Wit, ovaalvormige, bikonvekse, filmbedekte tablette gemerk met "T23" aan die een kant en glad aan die ander kant.
ARLOZYB CO TABLETS 5/160/25 mg: Geel, ovaalvormige, bikonvekse, filmbedekte tablette gemerk met "T25" aan die een kant en glad aan die ander kant.
ARLOZYB CO TABLETS 10/160/12,5 mg: Liggeel, ovaalvormige, bikonvekse, filmbedekte tablette gemerk met "C95" aan die een kant en glad aan die ander kant.
ARLOZYB CO TABLETS 10/160/25 mg: Geelbruin, ovaalvormige, bikonvekse, filmbedekte tablette gemerk met "C97" aan die een kant en glad aan die ander kant.
ARLOZYB CO TABLETS 10/320/25 mg: Geelbruin, ovaalvormige, bikonvekse, filmbedekte tablette gemerk met "T98" aan die een kant en glad aan die ander kant.

Inhoud van die pakkie:
1) Stulpverpakking:
Tablette word verpak in stulpe van koue vorm gelamineerde 25 µm OPA / 45 µm aluminiumfoelie / 60 µm PVC as die vormings materiaal en 30 µ gewone aluminium foelie/ 6-8 gsm hittesëëlak as die dekmateriaal, verpak in 'n voorafgedrukte karton.
Verpakkingsgroottes skult 7, 10, 14, 28, 56 of 98 tablette in.

2) HDPE-houer
30 tablette is verpak in ronde, wit 60 ml HDPE houer met 33-400 nekafwerking wat toegemaak is met 33 mm kinderbestande sluiting met pulp en hittesëël wit gedrukte voering.
Nie alle verpakkingsgroottes word noodwendig bemark nie.

Houer van Sertifikaat van Registrasie
MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Grondvloer, Blok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia-rylaan 1, Bassonia Rock Uittr 12
Alberton
Gauteng

Hierdie inligtingstuk is laas hersien in
05 Desember 2023

Registrasienommers
ARLOZYB CO TABLETS 5/160/12,5 mg : 56/7.1.3/0560
ARLOZYB CO TABLETS 5/160/25 mg : 56/7.1.3/0561
ARLOZYB CO TABLETS 10/160/12,5 mg : 56/7.1.3/0562
ARLOZYB CO TABLETS 10/160/25 mg : 56/7.1.3/0563
ARLOZYB CO TABLETS 10/320/25 mg : 56/7.1.3/0564

Toegang tot die ooreenstemmende professionele inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169

335 mm

MASTER COPY

MACLEODS

Restricted Circulation

PACKAGING RESEARCH & DEVELOPMENT

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: ARLOZYB CO TABLETS 5/160/12,5 mg, 5/160/25 mg, 10/160/12,5 mg, 10/160/25 mg, 10/320/25 mg (Amlodipine, Valsartan, HCTZ Tablets 5/160/12,5 mg, 5/160/25 mg, 10/160/12,5 mg, 10/160/25 mg, 10/320/25 mg	
2. Country: South Africa (Private Market)	3. Packaging component: Patient Information Leaflet
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 28 gsm bible paper	
7. Machine Layout No.: NA	8. Dimensions: 370 (L) x 335 (W) mm
9. Design / Style: Booklet	10. Item code No.: PM04273801
11. Artwork has been made: Actual Size	12. Pharma code No.: 33440 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: NA
15. Revision No: 00	16. AW File name: Z:\Amlodipine, Valsartan and HCLQ\1\Amlodipine, Valsartan, HCTZ Tab PIL- PM04273801.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
11/01/24	Vanita Rajool	12/01/24	22/01/24	25/01/24	22/01/24

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 Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa - Private Market	PM04273801		

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