APPROVED PIL

For

ARPLEXAM

Registration No.:

Arplexam 5/1,25/5 mg: 49/7.1.3/1238

Arplexam 5/1,25/10 mg: 49/7.1.3/1235

Arplexam 10/2,5/5 mg: 49/7.1.3/1236

Arplexam 10/2,5/10 mg: 49/7.1.3/1237

Date Approved: November 2020

Confidential Information

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S3**

Arplexam 5 mg/1,25 mg/5 mg film-coated tablets
Arplexam 5 mg/1,25 mg/10 mg film-coated tablets
Arplexam 10 mg/2,5 mg/5 mg film-coated tablets
Arplexam 10 mg/2,5 mg/10 mg film-coated tablets

perindopril arginine/ indapamide/ amlodipine

Read all of this leaflet carefully before you start taking Arplexam.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse or other healthcare provider.
- **Arplexam** 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 **Arplexam** is and what it is used for
2. What you need to know before you take **Arplexam**
3. How to take **Arplexam**
4. Possible side effects
5. How to store **Arplexam**
6. Content of the pack and other information

1. What Arplexam is and what it is used for

Arplexam is a combination of three active ingredients: perindopril, indapamide and amlodipine. It is an anti-hypertensive medicine used in the treatment of high blood pressure (hypertension). If you are already taking perindopril/indapamide as fixed dose combination and amlodipine from separate tablets you may instead receive one tablet of **Arplexam** which contains the three active ingredients in the same strength.
Each of the active ingredients reduces blood pressure and they work together to control your blood pressure:

- Perindopril belongs to a class of medicines called Angiotensin Converting Enzyme (ACE) inhibitors. It works by widening the blood vessels, which makes it easier for your heart to pump blood through them,
- Indapamide is a diuretic (which is a sulphonamide derivative). Diuretics increase the amount of urine produced by the kidneys. However, indapamide only causes a slight increase in the amount of urine produced,
- Amlodipine is a calcium channel blocker s (which belongs to a class of medicines called dihydropyridines). It works by relaxing blood vessels, so blood passes through easily.

2. What you need to know before you take Arplexam

Do not take Arplexam

- if you are hypersensitive (allergic) to perindopril or other ACE-inhibitors, indapamide or other sulphonamides, amlodipine or other dihydropyridines, or any of the other ingredients of **Arplexam** (listed in section 6),
- if you have experienced symptoms such as wheezing, with difficult breathing, swelling of the face or tongue, intense itching or severe skin rashes with previous ACE-inhibitor treatment or if you or a member of your family have had these symptoms in any other circumstances (a condition called angioedema),
- if you have a liver disease with moderate to severe impairment of your liver function or suffer from a condition called hepatic encephalopathy (disease of the brain caused by liver illness),
- if you are suspected of having untreated decompensated heart failure (severe water retention, difficulty in breathing),
- if you are treated with medicines that may cause serious heart rhythm disturbances,
- if you have narrowing of the aortic heart valve (aortic stenosis) or 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 have severe low blood pressure (hypotension),
- if you have a low blood potassium level,
- if you have severe kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis),
- if you have only one kidney
- if you are receiving dialysis or any other type of blood filtration. Depending on the machine that is used, **Arplexam** may not be suitable for you,
- if you have moderate or severe impairment of your kidney function,
- if you are pregnant or planning to become,
- if you are breastfeeding your baby,

- if you have porphyria,
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren,
- if you are being treated with sacubitril/valsartan, a medicine for heart failure (see "Warnings and Precautions" and "Other medicines and **Arplexam**"),
- If you are treated with Lithium,
- If you are treated with potassium sparing diuretics (water pills that increase your blood potassium e.g. spironolactone, triamterene).

Warnings and precautions

Tell your doctor or healthcare professional before taking **Arplexam.**

Take special care with **Arplexam**:

- if you have hypertrophic cardiomyopathy (heart muscle disease) or renal artery stenosis (narrowing of the artery supplying the kidney with blood),
- if you have heart failure or any other heart problems,
- if you have a severe increase in blood pressure (hypertensive crisis),
- if you have liver disease/disorder,
- if you suffer from a collagen disease (skin disease) such as systemic lupus erythematosus or scleroderma,
- if you have atherosclerosis (hardening of the arteries),
- if you need to have a test to check how well your parathyroid gland is working,
- if you suffer from gout,
- if you have diabetes mellitus,
- if you are on a salt restricted diet or use salt substitutes which contain potassium (a well-balanced potassium blood level is essential),
- if you take lithium or potassium-sparing diuretics (spironolactone, triamterene) as their use with **Arplexam** should be avoided (see "Taking other medicines"),
- if you are elderly and your dose needs to be increased,
- if you have had photosensitivity reactions,
- if you are of black origin the blood pressure lowering effect may be less and you may have a higher incidence of angioedema (swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing),
- if you are on haemodialysis dialysed with high-flux membranes,
- if you have a kidney disease/disorder or if you are receiving dialysis,
- if you have increased levels of a hormone called aldosterone in your blood (primary aldosteronism),

- if you have too much acid in blood, which may cause an increased rate of breathing,
- if you have cerebral circulatory insufficiency (low blood pressure and blood flow in the brain),
- if you have swelling of the face, lips, mouth , tongue or throat which may cause difficulty in swallowing or breathing (angioedema), which can occur at any time during treatment, stop your treatment immediately and directly contact your doctor.
- if you are taking any of the following medicines, the risk of angioedema is increased:
    - racecadotril (used to treat diarrhoea),
    - sirolimus, everolimus, temsirolimus and other medicine belonging to the class of so-called mTOR inhibitors (used to avoid rejection of transplanted organs),
    - sacubitril (available as fixed-dose combination with valsartan), used to treat long-term heart failure.
- if you are taking any of the following medicines used to treat high blood pressure:
    - an “angiotensin II receptor blocker” (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems
    - aliskiren.

  Your doctor may check your kidney function, blood pressure, and the concentration/levels of electrolytes (e.g. potassium) in your blood at regular intervals.
  See also information under the heading “Do not take **Arplexam**”.

Your doctor may request laboratory blood tests to check if you have a low sodium level, a low or potassium level or a high calcium level.

When you are taking **Arplexam**, you should also inform your doctor or the medical staff:

- if you are to undergo anaesthesia and/or surgery,
- if you have recently suffered from diarrhoea or vomiting, or are dehydrated,
- if you are to undergo dialysis or LDL apheresis (which is removal of cholesterol from your blood by a machine),
- if you are going to have desensitisation treatment to reduce the effects of an allergy to bee or wasp stings,
- if you are to undergo a medical test that requires injection of an iodinated contrast medicine (a substance that makes organs like kidney or stomach visible on an X-ray).

Children and adolescents

Arplexam should not be given to children and adolescents under the age of 18 years.

Other medicines and Arplexam

Always tell your healthcare professional if you are taking other medicines (this include complementary or traditional medicines).

Do not take aliskiren (used to treat high blood pressure) if you have diabetes or kidney diseases/disorders or just one kidney.
You should avoid **Arplexam** with:

- ✓ lithium (used to treat some mental health disorders such as mania, manic depressive illness and recurrent depression),
- ✓ potassium-sparing medicine (e.g. triamterene, amiloride), potassium supplements or potassium-containing salt substitutes, other medicines which can increase potassium in your body (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole),
- ✓ dantrolene (infusion) which is ~~also~~ used to treat malignant hyperthermia during anaesthesia (symptoms including very high fever and muscle stiffness),
- ✓ estramustine (used in cancer therapy),
- ✓ medicines, which are used to treat diarrhea (racecadotril) or to avoid rejection of transplanted organs (sirolimus, everolimus, temsirolimus and other medicines belonging to the class of so-called mTor inhibitors). See section “Warnings and precautions”,
- ✓ sacubitril/valsartan (used to treat long-term heart failure). See sections “Do not take **Arplexam**” and “Warnings and precautions”,
- ✓ other medicines used to treat high blood pressure: angiotensin-converting-enzyme inhibitor and angiotensin receptor blockers.

Treatment with **Arplexam** can be affected by other medicines. Your doctor may need to change your dose and/or to take other precautions. Make sure to tell your doctor if you are taking any of the following medicines as special care may be required:

- ✓ other medicines for treating high blood pressure, including angiotensin II receptor blocker (ARB), aliskiren (see also information under the headings “Do not take **Arplexam**” and “Warning and precaution”), or diuretics (medicines which increase the amount of urine produced by the kidneys),
- ✓ potassium-sparing medicines used in the treatment of heart failure: eplerenone and spironolactone at doses between 12,5 mg to 50 mg per day,
- ✓ anaesthetic medicines
- ✓ iodinated contrast medicines
- ✓ bepridil (used to treat angina pectoris),
- ✓ moxifloxacin, sparfloxacin (antibiotics: medicines used to treat infection),
- ✓ methadone (used to treat addiction)

- ✓ dofetilide, ibutilide, bretylium, cisapride, diphemanil, procainamide, quinidine, hydroquinidine, disopyramide, amiodarone, sotalol (for the treatment of an irregular heart beat),
- ✓ verapamil, diltiazem (heart medicines)
- ✓ digoxin (for the treatment of heart problems),
- ✓ rifampicin, erythromycin, clarithromycin (antibiotics for infection caused by bacteria),
- ✓ itraconazole, ketoconazole, amphotericin B by injection (to treat fungal disease),
- ✓ allopurinol (for the treatment of gout),
- ✓ mizolastine, terfenadine or astemizole (antihistamines for hay fever or allergies),
- ✓ corticosteroids used to treat various conditions including severe asthma and rheumatoid arthritis, and non-steroidal anti-inflammatory medicine (e.g. ibuprofen) or high dose salicylates (e.g. acetylsalicylic acid),
- ✓ immunosuppressants (medicines used to control your body's immune response) for the treatment of auto-immune disorders or following transplant surgery (e.g. ciclosporin, tacrolimus),
- ✓ tetracosactide (to treat Crohn's disease)
- ✓ gold salts, especially with intravenous administration (used to treat symptoms of rheumatoid arthritis),
- ✓ halofantrine (used to treat certain types of malaria),
- ✓ baclofen used to treat muscle stiffness in diseases such as multiple sclerosis,
- ✓ medicines to treat diabetes such as insulin or metformin,
- ✓ calcium including calcium supplements,
- ✓ stimulant laxatives (e.g. senna),
- ✓ medicines for the treatment of cancer,
- ✓ vincamine (used to treat symptomatic cognitive disorders in elderly including memory loss),
- ✓ medicines to treat mental health disorders such as depression, anxiety, schizophrenia…(e.g. tricyclic antidepressants, antipsychotics, imipramine-like antidepressants, neuroleptics),
- ✓ pentamidine (used to treat pneumonia),
- ✓ ritonavir, indinavir, nelfinavir (so called protease inhibitors used to treat HIV).
- ✓ hypericum perforatum (St. John's Wort),
- ✓ trimethoprim (for the treatment of infections),
- ✓ medicines used for the treatment of low blood pressure, shock or asthma (e.g. ephedrine, noradrenaline or adrenaline),
- ✓ nitroglycerin and other nitrates, or other vasodilators that may further reduce blood pressure.

Contact your doctor to re-evaluate your treatment if you are treated with a fluoroquinolone antibiotic and you are also on treatment with **Arplexam** or an angiotensin receptor blocker for your hypertension.

Athletes should be aware that **Arplexam** contains an active ingredient (indapamide) which is listed as a prohibited medicine for athletes to use (will give a positive test for prohibited substances).

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

Pregnancy and breastfeeding
You should not be treated with **Arplexam** if you think you are pregnant, if you are pregnant or plan to become pregnant, as **Arplexam** may cause serious harm to your unborn baby.
If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to become pregnant, ask your doctor or pharmacist for advice before taking **Arplexam.**

Breastfeeding
You should not breastfeed your baby if you are on treatment with **Arplexam** as harm to your baby cannot be excluded, and **Arplexam** may suppress or decrease the volume of breastmilk secreted.

Driving and using machinery
Arplexam may affect your ability to drive or use machines. You should not drive and use machines until you know how treatment with **Arplexam** is affecting you. **Arplexam** may cause a low blood pressure, dizziness, nausea, vision disturbances, fatigue, tiredness and headache.

Arplexam contains sodium
Arplexam contains less than 1 mmol sodium (23 mg) per tablet, essentially ‘sodium-free’.

3. How to take Arplexam
Do not share medicines prescribed for you with any other person.

Always take **Arplexam** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
Swallow the tablet with a glass of water preferably in the morning and before a meal. Your doctor will decide on the correct dose for you. This will be one tablet once a day.

If you take more Arplexam than you should
Taking too many tablets may cause you blood pressure to become low or even dangerously low sometimes associated with nausea, vomiting, cramps, dizziness, sleepiness, mental confusion, oliguria (passing less urine than is normal), anuria (no production or passing of urine). You may feel lightheaded, faint, or weak. If blood pressure drop is severe enough shock can occur. Your skin could feel cool and clammy and you could lose consciousness. Seek immediate medical care if you take too many **Arplexam** tablets.
In the event of an overdosage, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

If you forget to take Arplexam
It is important to take your medicine every day as regular treatment is more effective. However, If you forget to take a dose of **Arplexam**, take the next dose at the usual time.
Do not take a double dose to make up for forgotten individual doses.

If you stop taking Arplexam
As the treatment for high blood pressure is usually life-long, you should discuss your treatment with your doctor before stopping **Arplexam**.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects
Arplexam can have side effects.
Not all side effects reported for Arplexam are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Arplexam, please consult your doctor, pharmacist or other healthcare professional for advice.
Stop taking Arplexam and see a doctor immediately, if you experience any of the following side effects:

- sudden wheeziness, chest pain, shortness of breath, or difficulty in breathing (bronchospasm)

- swelling of eyelids, face or lips,
- swelling of the mouth, tongue and throat, which causes great difficulty 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 mucous membranes (Stevens Johnson Syndrome, toxic epidermal necrolysis) or other allergic reactions,
- severe dizziness or fainting,
- heart attack, unusual fast or abnormal heart beat, or life-threatening irregular beat.
- inflamed pancreas which may cause severe abdominal and back pain accompanied with feeling very unwell.

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

Tell your doctor if you notice any of the following:

***Frequent* side effects:**

Headache, dizziness, palpitations (awareness of your heartbeat), flushing, vertigo, pins and needles, vision disturbances (including double vision), tinnitus (sensation of noises in the ears), light-headedness due to low blood pressure, cough, shortness of breath, gastro-intestinal disorders (nausea, vomiting, abdominal pain, taste disturbances, dyspepsia or difficulty of digestion, diarrhoea, constipation), allergic reactions (such as skin rashes, itching), cramps, feeling of tiredness, somnolence, ankle swelling (oedema).

***Less frequent* side effects:**

Mood swings, anxiety, depression, sleep disturbances, trembling, hives, fainting, loss of pain sensation, rhinitis (blocked up or runny nose), altered bowel habits, hair loss, purpura (red pinpoints on skin), skin discoloration, itchy skin, sweating, chest pain, joint or muscle pain, back pain, pain, feeling unwell (malaise), kidney problems, disorder in passing urine, increased need to urinate at night, increased number of times of passing urine, inability to obtain an erection, fever or high temperature, discomfort or enlargement of the breasts in men, weight increase or decrease, increase in some white blood cells, high potassium levels in the blood, hypoglycaemia (very low blood sugar level), low sodium levels in the blood, rapid heartbeat, vasculitis (inflammation of blood vessels), photosensitivity reactions (change in skin appearance) after exposure to the sun or artificial UVA, blister clusters over the skin, swelling of hands, ankles or feet, blood creatinine increased and blood urea increase, fall, dry mouth. Confusion, changes in laboratory parameters: Increased level of liver enzymes, high level of serum bilirubin.

Decreased numbers of white blood cells, decrease in the number of platelets (which causes easy bruising and nasal bleeding), anaemia (decrease in red blood cells), cardiovascular

disorders (irregular heartbeat, angina pectoris (pains to the chest, jaw and back , brought on by physical effort, and due to problems with the blood flow to the heart), stroke), eosinophilic pneumonia (a rare type of pneumonia), swelling of the gums, severe skin reactions including intense skin rash, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, erythema multiforme (a skin rash which often starts with red itchy patches on your face, arms or legs), bleeding, tender or enlarged gums, abnormal liver function, inflammation of the liver (hepatitis), severe kidney problems, yellowing of the skin (jaundice), abdominal bloating (gastritis), disorder of the nerves which can cause weakness, tingling or numbness, increased muscle tension, hyperglycaemia, high level of calcium in the blood, cerebrovascular accident possibly secondary to excessive low blood pressure.
Hepatic encephalopathy (disease of the brain caused by liver illness), abnormal ECG heart tracing, low potassium levels in the blood, if you suffer from systemic lupus erythematous (a type of collagen disease), this might get worse.
Short sightedness (myopia), vision blurred,
Trembling, rigid posture, mask like face, slow movements and a shuffling, unbalanced walk.
Discoloration, numbness and pain in fingers or toes (Raynaud's phenomenon).
Changes in laboratory parameters (blood tests) can occur. Your doctor may request blood tests to monitor your condition.
Concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate ADH (anti-diuretic hormone) secretion which can occur with ACE-inhibitors. If you have these symptoms contact your doctor as soon as possible.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. 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 **Arplexam**.

5. How to store Arplexam

Store at or below 30 °C.
Store all medicine out of reach of children.
Keep the bottle well closed to protect the tablets from moisture.
Do not store in bathrooms.

Do not use after the expiry date on the carton and the bottle. The expiry date refers to the last day of that month.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

Arplexam does not require any special storage conditions.

6. Content of the pack and other information

What Arplexam contains

- The active substances are perindopril arginine, indapamide and amlodipine.
  One film-coated tablet of:
  - **Arplexam 5/1,25/5 mg** contains 3,395 mg perindopril equivalent to 5mg perindopril arginine, 1,25 mg indapamide and 6,935mg amlodipine besilate equivalent to 5 mg of amlodipine.
  - **Arplexam 5/1,25/10 mg** contains 3,395 mg perindopril equivalent to 5mg perindopril arginine, 1,25 mg indapamide and 13,870mg amlodipine besilate equivalent to 10 mg of amlodipine.
  - **Arplexam 10/2,5/5 mg** contains 6,790 mg perindopril equivalent to 10 mg perindopril arginine, 2,5 mg indapamide and 6,935mg amlodipine besilate equivalent to 5 mg of amlodipine.
  - **Arplexam 10/2,5/10 mg** contains 6,790 mg perindopril equivalent to 10 mg perindopril arginine, 2,5 mg indapamide and 13,870 mg amlodipine besilate equivalent to 10 mg of amlodipine.
- The other ingredients are:
  - Tablet core: Calcium carbonate starch compound: Calcium carbonate 90 %, Pregelatinised maize starch 10 %, cellulose microcrystalline (E460), croscarmellose sodium (E468), magnesium stearate (E572), colloidal anhydrous silica, pregelatinised starch.
  - Tablet film-coating: Glycerol(E422), hypromellose 6mPa.s (E464), macrogol 6 000, magnesium stearate (E572), titanium dioxide (E171).

What Arplexam looks like and contents of the pack

Arplexam 5/1,25/5 mg are white, oblong, film-coated tablet, 9,75 mm long and 5,16 mm wide, engraved with  on one face and  on the other face.

Arplexam 5/1,25/10 mg are white, oblong, film-coated tablet, 10,7 mm Long and 5,66 mm wide, engraved with  on one face and on the other face.

Arplexam 10/2,5/5 mg are white, oblong, film-coated tablet, 11,5 mm long and 6,09 mm wide, engraved with  on one face and  on the other face.

Arplexam 10/2,5/10 mg are white, oblong, film-coated tablet, 12,2 mm long and 6,46 mm, engraved with  on one face and  on the other face.

Tablet container of 30 film-coated tablets white polypropylene tablet container and a white opaque stopper containing a desiccant gel placed into a carton.

Holder of Certificate of Registration

Servier Laboratories South Africa (Pty) Ltd
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Namibia Details

Arplexam 5/1,25/5:	16/7.1.3/0021 (NS2)
Arplexam 5/1,25/10:	16/7.1.3/0020 (NS2)
Arplexam 10/2,5/5:	16/7.1.3/0019 (NS2)
Arplexam 10/2,5/10:	16/7.1.3/0018 (NS2)

Botswana Details

Arplexam 5/1,25/5:	BOT1602903 (S2)
Arplexam 5/1,25/10:	BOT1602904 (S2)
Arplexam 10/2,5/5:	BOT1602905 (S2)
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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S3

Arplexam 5mg/1,25mg/5mg filmbedekte tablette
Arplexam 5mg/1,25mg/10mg filmbedekte tablette
Arplexam 10mg/2,5mg/5mg filmbedekte tablette
Arplexam 10mg/2,5mg/10mg filmbedekte tablette

perindopriel arginien/indapamied/amlodipien

Lees die hele pamflet deeglik deur voordat jy Arplexam begin neem.
- Hou hierdie pamflet. Dit is moontlik dat jy dit weer sal wil lees.
- Indien jy enige verdere vrae het, vra jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- **Arplexam** is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

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

1. Wat Arplexam is en waarvoor dit gebruik word

Arplexam is 'n kombinasie van drie aktiewe bestanddele: perindopriel, indapamied en amlodipien. Dit is 'n anti-hipertensiewe medisyne wat by die behandeling van hoë bloeddruk (hipertensie) gebruik word.

As jy alreeds perindopriel/indapamied as 'n vaste-dosis kombinasie en amlodipien as aparte tablette neem, kan jy in plaas daarvan een tablet **Arplexam**, wat die drie aktiewe bestanddele in dieselfde sterkte bevat, ontvang.

Elke aktiewe bestanddeel verlaag die bloeddruk en werk saam om jou bloeddruk te beheer:

- Perindopriel behoort aan 'n klas van medisyne genaamd angiotensien-omsettingsensiem (AOE)- remmers. Dit werk deur die bloedvate te verwyd, wat dit dan vir jou hart makliker maak om bloed daardeur te pomp.
- Indapamied is 'n diuretikum (wat 'n sulfoonamied derivaat is) Diuretika verhoog die hoeveelheid urien wat deur die niere geproduseer word. Indapamied het 'n effense toename in die hoeveelheid urien veroorsaak.
- Amlodipien is 'n kalsiumkanaalblokker (wat behoort aan 'n klas van medisyne genaamd dihidropiridiene). Dit werk deur die bloedvate te verslap, sodat bloed maklik kan deurvloei.

2. Wat jy moet weet voordat jy Arplexam neem

Moenie Arplexam neem nie

- as jy hipersensitief (allergies) is vir perindopriel of ander AOE-remmers, indapamied of ander sulfoonamiede, amlodipien of ander dihidropiridiene, of enige van die ander bestanddele van **Arplexam** (gelys in Afdeling 6),
- as jy simptome ervaar het soos hyging, met moeilik asemhaling, swelling in die gesig of tong, intense jeuk of erge veluitslag tydens 'n vorige behandeling met 'n AOE-remmer, of as jy of 'n familielid hierdie simptome onder enige ander omstandighede ervaar het ('n toestand genaamd angio-edeem),
- as jy matig tot erge lewersiekte het of aan 'n toestand genaamd lewerensefalopatie ly ('n breinsiekte wat deur lewersiekte veroorsaak word),
- as daar vermoed word dat jy onbehandelde gedekompenseerde hartversaking het (ernstige vogretensie, asemhalingsprobleme),
- as jy behandel word met medisynes wat erge hartklop versteurings kan veroorsaak,
- as jy 'n vernouing van die aorta-hartklep (aorta-stenose) het, of kardiogene skok ('n toestand waar jou hart nie genoeg bloed aan die liggaam kan voorsien nie),
- as jy ly aan hartversaking na 'n hartaanval,
- as jy erge lae bloeddruk (hipotensie) het,
- as jy 'n lae bloedkalium vlak het,
- as jy erge nierprobleme het waar die bloedtoevoer na die niere verminder is (nieraar stenose),
- as jy net een nier het,
- as jy dialise ontvang of enige ander tipe bloed filtrasie. Afhangend van die masjien wat gebruik word, is **Arplexam** moontlik nie geskik vir jou nie,
- as jy matige of erge nierprobleme het,
- as jy swanger is of beplan om swanger te raak,
- as jy jou baba borsvoed,

- as jy porfirie het,
- as jy diabetes of verswakte nierfunksie het en jy word behandel met 'n bloeddrukverlagende medisyne wat aliskiren bevat,
- as jy behandel word met sakubitriel/valsartaan, 'n medisyne vir hartversaking (kyk "Waarskuwings en voorsorgmaatreëls" en "Ander medisynes en **Arplexam**"),
- as jy met Litium behandel word,
- as jy behandel word met kaliumsparended diuretika (watter pille wat jou bloedkalium verhoog bv. spironolaktoon, triamtereen).

Waarskuwings en voorsorgmaatreëls

Vertel jou dokter of gesondheidsorg professioneel voor jy **Arplexam** neem.

Spesiale voorsorg met **Arplexam**:

- as jy hipertrofiese kardiomiopatie (hartspiersiekte) of nieraar stenose het (vernouing van die slagaar wat die nier van bloed voorsien),
- as jy hartversaking het, of enige ander hartprobleme,
- as jy 'n erge toename in bloeddruk het (hipertensiewe krisis),
- as jy lewersiekte/wanorde het,
- as jy aan 'n kollageensiekte (velsiekte) ly, soos sistemiese lupus eritematose of sklerodermie,
- as jy aterosklerose het (verharding van die arterieë),
- as jy 'n toets moet kry om te kontroleer hoe goed jou byskildklier werk,
- as jy aan jig ly,
- as jy diabetes mellitus het,
- as jy op 'n sout beperkende dieet is of soutvervangings gebruik wat kalium bevat ('n goed-gebalanseerde bloedvlak is noodsaaklik),
- as jy litium of kaliumsparende diuretika (spironolaktoon, triamtereen) neem, want die gebruik hiervan saam met **Arplexam** moet vermy word (kyk "Ander medisynes en **Arplexam**"),
- as jy bejaard is en jou dosis moet verhoog word,
- as jy reaksies vanweë liggevoeligheid gehad het,
- as jy van swart oorsprong is mag die bloeddruk verlagende effek minder wees en jy mag 'n hoër voorkoms van angio-edeem kry (swelling in die gesig, lippe, mond, tong of keel wat kan veroorsaak dat jy sukkel om te sluk of asem te haal),
- as jy op hemodialise is en met hoë-vloeimembrane gedialiseer word,
- as jy nierprobleme het of dialise ontvang,

- as jy verhoogde vlakke van 'n hormoon genaamd aldosteroon in jou bloed het (primêre aldosteronisme),
- as jy te veel suur in jou bloed het, wat 'n verhoogde asemhalingstempo kan veroorsaak,
- as jy ontoereikende serebrale bloedsomloop het (lae bloeddruk en bloedvloei in die brein),
- as jy swelling in die gesig, lippe, mond, tong of keel het wat dit moeilik kan maak om te sluk of asem te haal (angio-edeem), wat op enige tydstip tydens die behandeling kan voorkom, moet jy die behandeling dadelik staak en jou dokter onmiddellik kontak.
- As jy een van die volgende medisynes gebruik, verhoog die risiko van angio-edeem:
- rasekadotriel (gebruik om diarree te behandel),
- sirolimus, everolimus, temsirolimus en ander medisyne wat aan die klas van sogenaamde mTor-remmers behoort (word gebruik om verwerping van oorgeplante organe te keer),
- sakubitriel (beskikbaar as 'n vaste-dosis kombinasie met valsartaan), gebruik om langtermyn hartversaking te behandel.
- as jy enige van die volgende medisynes neem om hoë bloeddruk te behandel:
- 'n "angiotensien-II reseptorblokker" (ARB) (ook bekend as sartane - byvoorbeeld valsartaan, telmisartaan, irbesartaan), veral as jy suikerverwante nierprobleme het.
- aliskiren.

Jou dokter kan jou nierfunksie, bloeddruk en die konsentrasie/vlakke van elektroliete (bv. kalium) in jou bloed met gereelde tussenposes nagaan.
Kyk ook na die inligting onder die opskrif "Moenie **Arplexam** neem nie".

Jou dokter kan vir jou bloedtoetse voorskryf om te kontroleer of jy lae natrium- of kaliumvlakke of hoë kalsiumvlakke het.
Wanneer jy **Arplexam** neem, moet jy ook jou dokter of die mediese personeel inlig:

- as jy narkose en/of 'n operasie moet ondergaan,
- as jy onlangs aan diarree of braking gely het of jy gedehidreer is,
- as jy dialise of LDL-aferese moet ondergaan (dit is die verwydering van cholesterol uit jou bloed deur 'n masjien),
- as jy 'n desensitiseringbehandeling moet kry om die effekte van 'n allergie vir by- of perdebysteke te verminder,
- as jy 'n mediese toets moet ondergaan wat die inspuit van 'n jodiumkontras medisyne ('n middel wat organe soos die nier of maag op 'n X-straal sigbaar maak) benodig.

Kinders en adolessente

Arplexam moet nie aan kinders en adolessente onder die ouderdom van 18 jaar gegee word nie.

Ander medisynes en Arplexam

Lig altyd jou gesondheidsorgkundige in as jy enige ander medisynes neem (dit sluit in komplementêre of tradisionele medisynes).

Moenie aliskiren (vir behandeling van hoë bloeddruk) neem as jy diabetes of niersiekte/wanorde of net een nier het nie.

Jy moet **Arplexam** vermy met:

- litium (gebruik om sommige geestesversteurings soos manie, manies-depressiewe siekte en herhalende depressie te behandel),
- kaliumsparende medisyne (bv. triamtereen, amiloried), kaliumaanvullings of kaliumbevattende soutvervangers, ander medisyne wat kalium in jou liggaam kan verhoog (soos heparien en ko-trimoksasool, ook bekend as trimetoprim/sulfametoksasool),
- dantroleen (infusie) wat gebruik word vir die behandeling van kwaadaardige hipertermie tydens narkose (simptome sluit in baie hoë koors en spierstyfheid),
- estramustien (gebruik by kankerbehandeling),
- medisynes wat meestal gebruik word om diarree te behandel (rasekadotriel), of om verwerping van oorgeplante organe (sirolimus, everolimus, temsirolimus en ander medisyne wat aan die klas van sogenaamde mTor-remmers behoort) te voorkom. Kyk afdeling "Waarskuwings en voorsorgmaatreëls",
- sakubitriel/valsartaan (gebruik om langtermyn hartversaking te behandel). Kyk afdelings "Moenie **Arplexam** neem nie" en "Waarskuwings en voorsorgmaatreëls",
- ander medisynes wat gebruik word om hoë bloeddruk te behandel: angiotensien-omsettingsensiemremmer en angiotensien-reseptorblokkers.
- Behandeling met **Arplexam** kan deur ander medisynes geaffekteer word. Jou dokter sal dalk jou dosis moet verander en/of ander voorsorgmaatreëls neem. Maak seker dat jy jou dokter inlig as jy enige van die volgende medisynes neem, want spesiale voorsorg kan nodig wees:
- ander medisynes vir die behandeling van hoë bloeddruk, insluitend die angiotensien-II -reseptorblokker (ARB), aliskiren (kyk ook inligting onder die opskrifte "Moenie **Arplexam** neem nie" en "Waarskuwings en voorsorgmaatreëls"), of diuretika (medisyne wat die hoeveelheid urien wat deur die niere geproduseer word, verhoog),
- kaliumsparende medisyne wat gebruik word by die behandeling van hartversaking: eplerenoon en spironolaktoon by dosisse tussen 12,5 mg tot 50 mg per dag,
- narkosemiddels,
- jodium kontras medisyne,
- bepridiel (gebruik vir behandeling van angina pectoris),

- moksifloksasien, sparfloksasien (antibiotika: medisyne wat gebruik word om infeksie te behandel),
- metadoon (gebruik om verslawing te behandel),
- dofetilied, ibutilied, bretilium, sisapried, difemamiel, prokaïenamied, kinidien, hidrokinidien, disopiramied, amiodaroon, sotalol (vir die behandeling van onreëlmatige hartklop),
- verapamiel, diltiasem (hartmedisynes),
- digoksien (vir die behandeling van hartprobleme),
- rifampisien, eritromisien, klaritromisien (antibiotika vir infeksie veroorsaak deur bakterieë),
- itrakonasool, ketokonasool, amfoterisien-B inspuiting (om swaminfeksie te behandel),
- allopurinol (vir die behandeling van jig),
- misolastien, terfenadien of astemisool (antihistamiene vir hooikoors of allergieë),
- kortikosteroïede wat gebruik word om verskillende toestande te behandel, insluitend ernstige asma en rumatoïede artritis, en niesteroïdale anti-inflammatoriese medisyne (bv. ibuprofeen) of hoë dosis salisilate (bv. asetielsalisielsuur),
- immuunonderdrukkers (medisyne wat gebruik word om jou immuunrespons in jou liggaam te beheer) vir die behandeling van outo-immuunafwykings of na 'n oorplantingsoperasie (bv. siklosporien, takrolimus),
- tetrakosaktiede (om Crohn se siekte te behandel),
- goud soute, veral met intraveneuse toediening (gebruik om simptome van rumatoïede artritis te behandel),
- halofantrien (gebruik om sekere tipes malaria te behandel),
- baklofeen wat gebruik word om spierstyfheid in siektes soos veelvuldige sklerose te behandel,
- medisynes soos insulien of metformien wat gebruik word om diabetes te behandel,
- kalsium, insluitende kalsiumaanvullings,
- prikkelende lakseermiddels (bv. senna),
- medisynes vir die behandeling van kanker,
- vinkamien (gebruik om simptomatiese kognitiewe afwykings, waaronder geheueverlies, by bejaardes te behandel),
- medisynes vir die behandeling van geestesversteurings soos depressie, angs, skisofrenie (bv. trisikliese antidepressante, antipsigotika, imipramienagtige antidepressante, neuroleptika),
- pentamidien (gebruik om pneumonie te behandel),
- ritonavir, indinavir, nelfinavir (sogenaamde proteasoomremmers wat gebruik word om menslike immuniteitsgebrekvirus (MIV) te behandel),
- *Hypericum perforatum* (Sint-johanneskruid),

- trimetoprim (vir die behandeling van infeksies),
- medisynes wat gebruik word vir die behandeling van lae bloeddruk, skok of asma (bv. efedrien, noradrenalien of adrenalien),
- nitrogliserien en ander nitrate, of ander vaatverwyders wat bloeddruk verder kan verlaag.

Kontak jou dokter om jou behandeling te herevalueer as jy met 'n fluoorkinoloon -antibiotikum behandel word en jy is ook op behandeling met **Arplexam** of ‘n angiotensienblokker vir jou hipertensie.

Atlete moet daarop let dat **Arplexam** 'n aktiewe bestanddeel (indapamied) bevat wat gelys is as ‘n verbode medisyne vir atlete om te gebruik (sal ‘n positiewe reaksie vir verbode middels lewer).

Arplexam met kos en vloeistof
Pomelosap en pomelo's moet nie ingeneem word deur mense wat **Arplexam** neem nie. Dit is omdat pomelo en pomelosap kan lei tot 'n toename in die bloedvlakke van die aktiewe bestanddeel amlodipien, wat 'n onvoorspelbare toename in die bloeddrukverlagende effek van **Arplexam** kan veroorsaak.

Swangerskap en borsvoeding
Jy moet nie behandel word met **Arplexam** as jy dink jy is swanger, as jy swanger is of beplan om swanger to word, aangesien **Arplexam** ernstige skade vir jou ongebore baba mag hê. As jy swanger is of jou baba borsvoed, dink dat jy swanger kan wees, of beplan om swanger te word, vra jou dokter of apteker om raad voordat jy **Arplexam** neem.

Borsvoeding
Jy moet nie jou baba borsvoed as jy op behandeling met **Arplexam** is nie, aangesien skade vir jou baba nie uitgesluit kan word nie, en **Arplexam** mag die volume borsmelk wat uitgeskei word, verminder.

Motorbestuur en gebruik van masjinerie
Arplexam kan jou vermoë om te bestuur of masjinerie te gebruik aantas. Jy moet nie bestuur of masjinerie gebruik totdat jy weet hoe behandeling met **Arplexam** jou beïnvloed**. Arplexam** mag a lae bloeddruk, duiseligheid, naarheid, visie versteurings, uitputting, moegheid en hoofpyn veroorsaak

Arplexam bevat natrium.

Arplexam bevat minder as 1 mmol natrium (23 mg) per tablet, in wese 'natriumvry'.

3. Hoe om Arplexam te neem

Moenie medisyne wat vir jou voorgeskryf is met 'n ander persoon deel nie.
Neem **Arplexam** altyd presies soos jou dokter dit vir jou voorgeskryf het. As jy onseker is, vra jou dokter of apteker.
Sluk die tablet met 'n glas water, verkieslik in die oggend en voor 'n maaltyd. Jou dokter sal op die regte dosis vir jou besluit. Dit sal gewoonlik een tablet een keer daagliks wees.

Indien jy meer Arplexam geneem het as wat jy moes
As jy te veel tablette inneem, kan dit veroorsaak dat jou bloeddruk laag word of selfs gevaarlik laag word, soms geassosieer met naarheid, braking, krampe, duiseligheid, slaperigheid, verstandelike verwardheid, oligurie (minder urien passeer as normaal), anurie (geen produksie van urien of urinering nie). Jy kan lighoofdig, flou of swak voel. Indien die bloeddruk daling erg genoeg is kan skok intree. Jou vel kan koel en klam voel en jy kan jou bewussyn verloor. Kry dadelik mediese hulp as jy te veel **Arplexam** tablette geneem het.
In die geval van oordosering, raadpleeg jou dokter of apteker. Indien geeneen beskikbaar is nie, kontak die naaste hospitaal of vergiftigingsentrum.

Indien jy vergeet het om Arplexam te neem
Dit is belangrik om jou medisyne elke dag te neem aangesien gereelde behandeling meer doeltreffend is. Indien jy egter vergeet om 'n dosis van **Arplexam** te neem, neem die volgende dosis op die gewone tyd.
Moenie 'n dubbeldosis neem om op te maak vir vergete individuele dosisse nie.

Indien jy ophou om Arplexam te neem
Aangesien die behandeling van hoë bloeddruk gewoonlik lewenslank is, moet jy dit met jou dokter bespreek voordat jy **Arplexam** stop.
Indien jy enige verder vrae het oor die gebruik van hierdie medisyne, vra jou dokter, apteker of verpleegster.

4. Moontlike newe-effekte

Arplexam kan newe-effekte hê.

Nie alle newe-effekte wat vir **Arplexam** aangemeld is, is by hierdie inligtingsblad ingesluit nie. Indien jou algemene gesondheid agteruitgaan of jy enige ongunstige effekte ervaar terwyl jy **Arplexam** neem, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgkundige.
Hou op om **Arplexam** te neem en gaan onmiddellik na 'n dokter as jy een van die volgende newe-effekte ervaar:

- skielike hyging, borspyn, kortasemigheid of asemhalingsprobleme (brongospasma),
- swelling van die ooglede, gesig of lippe,
- swelling van die mond, tong en keel, wat groot probleme met asemhaling veroorsaak,
- erge velreaksies, waaronder erge veluitslag, netelroos, rooi vel oor jou hele liggaam, erge jeuk, blase, afskilfering en swelling van die vel, ontsteking van die slymvliese (Stevens Johnson-sindroom, toksiese epidermale nekrolise) of ander allergiese reaksies,
- erge duiseligheid of floute,
- hartaanval, ongewone vinnige of abnormale hartslag, of lewensbedreigende ongereelde hartslag,
- ontsteekte pankreas wat erge buikpyn en rugpyn gepaard met 'n ongestelde gevoel kan veroorsaak.

Hierdie is almal ernstige newe-effekte. Jy kan dringende mediese aandag benodig.
Lig jou dokter in as jy enige van die volgende waarneem:

Gereelde newe-effekte:
Hoofpyn, duiseligheid, hartkloppings (bewus wees van jou hartklop), bloos, duiseligheid, spelde-en-naalde gevoel, gesigsversteurings (insluitend dubbelsig), tinnitus (gevoel van geluide in die ore), lighoofdigheid as gevolg van lae bloeddruk, hoes, kortasemigheid, gastro-intestinale afwykings (naarheid, braking, buikpyn, smaakversteurings, sooibrand of probleme met spysvertering, diarree, hardlywigheid), allergiese reaksies (soos veluitslag, jeuk), krampe, moegheid, slaperigheid, geswelde enkels (edeem).

Minder algemene newe-effekte:
Gemoedskommelings, angs, depressie, slaapversteurings, bewing, netelroos, floute, verlies van gevoeligheid vir pyn, rinitis (verstopte of loopneus), veranderde derm gewoontes, haarverlies, purpura (rooi punte op die vel), verkleuring van die vel, jeukerige vel, sweet, borspyn, gewrigs- of spierpyn, rugpyn, pyn, ongesteldheid (malaise), nierprobleme, probleme met urinering, verhoogde behoefte aan urinering in die nag, verhoogde aantal kere om te urineer, onvermoë om 'n ereksie te kry, koors of hoë temperatuur, ongemak of vergroting van die borste by mans, gewigstoename of afname, toename in sommige witbloedselle, hoë kaliumvlakke in die bloed,

hipoglukemie (baie lae bloedsuikervlak), lae natriumvlakke in die bloed, vinnige hartklop, vaskulitis (ontsteking van die bloedvate), liggevoeligheidsreaksies (verandering in die voorkoms van die vel) na blootstelling aan die son of kunsmatige UVA, blase in die vel, swelling van hande, enkels of voete, verhoogde kreatinien in die bloed en toename in bloedureum, val, droë mond.
Verwarring, veranderinge in laboratorium parameters: verhoogde vlak van lewerensieme, hoë vlak van serum bilirubien.
Verminderde aantal witbloedselle, afname in die aantal bloedplaatjies (wat maklik kneusplekke en neusbloeding veroorsaak), bloedarmoede (afname in rooibloedselle), kardiovaskulêre afwykings (onreëlmatige hartklop, angina pectoris (pyn op die bors, kakebeen en rug, veroorsaak deur liggaamlike inspanning, en as gevolg van probleme met die bloedtoevoer na die hart), beroerte), eosinofiliese longontsteking ('n seldsame soort longontsteking), swelling van die tandvleis, ernstige velreaksies, waaronder intense veluitslag, velrooiheid oor jou hele liggaam, erge jeuk, blase, afskilfering en swelling van die vel, multiforme eriteem ('n veluitslag wat dikwels begin met rooi jeukende kolle op jou gesig, arms of bene), bloeding, sagte of vergrote tandvleis, abnormale lewerfunksie, ontsteking van die lewer (hepatitis), erge nierprobleme, vergeling van die vel (geelsug), opgeblaasde buik (gastritis), senuweeversteurings wat swakheid, tinteling of gevoelloosheid kan veroorsaak, verhoogde spierspanning, hiperglukemie, hoë vlak van kalsium in die bloed, serebrovaskulêre ongeluk moontlik sekondêr tot uiterste lae bloeddruk.
Lewerensefalopatie (breinsiekte wat veroorsaak word deur lewersiekte), abnormale EKG-hartaftasting, lae kaliumvlakke in die bloed, as jy aan sistemiese lupus eritematose ly ('n soort kollageensiekte), kan dit erger word.
Kortsigtigheid (miopie), dowwe visie,
Bewing, rigiede houding, maskeragtige gesig, stadige bewegings en 'n skuifelende, ongebalanseerde stap.
Verkleuring, gevoelloosheid en pyn in vingers of tone (Raynaud se verskynsel).
Veranderings in laboratorium parameters (bloedtoetse) kan voorkom. Jou dokter sal moontlik vra dat jy bloedtoetse ondergaan om jou toestand te moniteer.
Gekonsentreerde urien (donker van kleur), naarheid of braking, spierkrampe, verwarring en stuipe wat die gevolg kan wees van onvanpaste ADH (antidiuretiese hormoon) afskeiding wat met AOE-remmers kan voorkom. Indien jy hierdie simptome het, kontak jou dokter sodra moontlik.
Indien jy enige newe-effekte opmerk wat nie in hierdie pamflet vermeld word nie, lig jou dokter of apteker in.

Aanmelding van newe-effekte

Indien jy enige newe-effekte ervaar, praat met jou dokter, apteker of verpleegster. Dit sluit enige moontlike newe-effekte in wat nie in hierdie pamflet gelys word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn onder SAHPRA se publikasies verskyn: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan jy meer inligting verskaf oor die veiligheid van **Arplexam**.

5. Hoe om Arplexam te bewaar

Bewaar by of onder 30 °C.

Bewaar alle medisyne buite bereik van kinders.

Hou die bottel diggeslote om die tablette teen vog te beskerm.

Moenie in badkamers bewaar nie.

Moenie na die vervaldatum wat op die kartonhouer en bottel verskyn, neem nie. Die vervaldatum dui op die laaste dag van daardie maand.

Neem alle ongebruikte medisyne terug na jou apteker.

Moenie ongebruikte medisyne in afvoerpype en rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pakkie en ander inligting

Wat Arplexam bevat

- Die aktiewe bestanddele is perindopriel arginien, indapamied en amlodipien.
  Een filmbedekte tablet van:
- **Arplexam 5/1,25/5 mg** bevat 3,395 mg perindopriel gelykstaande aan 5 mg perindopriel arginien, 1,25 mg indapamied en 6,935 mg amlodipienbesilaat gelykstaande aan 5 mg amlodipien.
- **Arplexam 5/1,25/10 mg** bevat 3,395 mg perindopriel gelykstaande aan 5 mg perindopriel arginien, 1,25 mg indapamied en 13,870 mg amlodipienbesilaat gelykstaande aan 10mg amlodipien.
- **Arplexam 10/2,5/5 mg** bevat 6,790 mg perindopriel gelykstaande aan 10 mg perindopriel arginien, 2,5 mg indapamied en 6,935 mg amlodipienbesilaat gelykstaande aan 5 mg amlodipien.
- **Arplexam 10/2,5/10 mg** bevat 6,790 mg perindopriel gelykstaande aan 10 mg perindopriel arginien, 2,5 mg indapamied en 13,870 mg amlodipienbesilaat gelykstaande aan 10 mg amlodipien.

- Die ander bestanddele is:

- Tabletkern: Kalsiumkarbonaat styselverbinding: Kalsiumkarbonaat 90 %, pregelatineerde mieliestysel 10 %, mikrokristallyne sellulose (E460), natrium-kroskarmellose (E468), magnesiumstearaat (E572), kolloïdale anhidriese silika, pregelatineerde stysel.
- Tablet filmbedekking: Gliserol (E422), hipromellose 6mPa.s (E464), makrogol 6 000, magnesiumstearaat (E572), titaandioksied (E171).

Hoe Arplexam lyk en wat die inhoud van die pakkie is

Arplexam 5/1,25/5 mg is 'n wit, langwerpige, filmbedekte tablet, 9,75 mm lank en 5,16 mm breed, gegraveer met  op die een kant en  op die ander kant.

Arplexam 5/1,25/10 mg is 'n wit, langwerpige, filmbedekte tablet, 10,7 mm lank en 5,66 mm breed, gegraveer met  op die een kant en  op die ander kant.

Arplexam 10/2,5/5 mg is 'n wit, langwerpige, filmbedekte tablet, 11,5 mm lank en 6,09 mm breed, gegraveer met  op die een kant en  op die ander kant.

Arplexam 10/2,5/10 mg is 'n wit, langwerpige, filmbedekte tablet, 12,2 mm lank en 6,46 mm breed, gegraveer met  op die een kant en  op die ander kant.

Tablethouer met 30 filmbedekte tablette, wit polipropileen tablethouer en 'n wit ondeursigtige prop wat 'n droogmiddel-jel bevat, in 'n karton geplaas.

Houer van die registrasiesertifikaat

Servier Laboratories South Africa (Pty) Ltd

Gebou nommer 4

Country Club Estate

Woodlands Drive 21

Woodmead

2191

Hierdie pamflet was voorheen hersien in

Registrasienommers

Arplexam 5/1,25/5 mg: 49/7.1.3/1238

Arplexam 5/1,25/10 mg: 49/7.1.3/1235

Arplexam 10/2,5/5 mg: 49/7.1.3/1236

Arplexam 10/2,5/10 mg: 49/7.1.3/1237

Registered Approved PIL

Applicant: Servier Laboratories SA (Pty) Ltd
Product: **Arplexam**
Date of submission: 24 November 2020

Namibia Details

Arplexam 5/1,25/5:	16/7.1.3/0021 (NS2)
Arplexam 5/1,25/10:	16/7.1.3/0020 (NS2)
Arplexam 10/2,5/5:	16/7.1.3/0019 (NS2)
Arplexam 10/2,5/10:	16/7.1.3/0018 (NS2)

Botswana Details

Arplexam 5/1,25/5:	BOT1602903 (S2)
Arplexam 5/1,25/10:	BOT1602904 (S2)
Arplexam 10/2,5/5:	BOT1602905 (S2)
Arplexam 10/2,5/10:	BOT1602906 (S2)