PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

ZYVASC 5/160 mg film-coated tablets (5 mg amlodipine and 160 mg valsartan)

ZYVASC 10/160 mg film-coated tablets (10 mg amlodipine and 160 mg valsartan)

Amlodipine and valsartan

Sugar free.

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

- 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.
- ZYVASC 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 ZYVASC is and what it is used for
2. What you need to know before you take ZYVASC
3. How to take ZYVASC
4. Possible side effects
5. How to store ZYVASC
6. Contents of the pack and other information.

1. What ZYVASC is and what it is used for

ZYVASC contains two substances, called amlodipine and valsartan. Both of these substances help to control high blood pressure.

Amlodipine belongs to a group of substances called “calcium channel blockers”. Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening.

Valsartan belongs to a group of substances called “angiotensin II receptor antagonists”. Angiotensin II is produced by the body and makes the blood vessels tighten, thus increasing the blood pressure. Valsartan works by blocking the effect of angiotensin II.

This means that both of these substances help to stop the blood vessels tightening. As a result, the blood vessels relax and blood pressure is lowered.

ZYVASC is used to treat high blood pressure in adults whose blood pressure is not controlled enough with either amlodipine or valsartan on its own.

2. What you need to know before you take ZYVASC

Do not take ZYVASC

- If you are hypersensitive (allergic) to amlodipine or any other calcium channel blockers, valsartan or to any of the other ingredients of ZYVASC (listed in section 6).
- If you have experienced swelling, particularly of the face and throat, while taking other medicines (including angiotensin-converting enzyme inhibitors). If you get these symptoms, stop taking ZYVASC and contact your doctor straight away. You should never take ZYVASC again.
- If you have recurrent episodes of severe swelling without a known cause.
- If your doctor has diagnosed that you are suffering from a narrowing of valves in your heart (called aortic or mitral stenosis), or abnormally increased thickness of your heart muscle with narrowing (called obstructive hypertrophic cardiomyopathy).
- If you have received a kidney transplant or if you had been diagnosed to suffer from a narrowing of your kidney artery or if you are suffering from severe kidney problems.
- If you are taking other medicine or substances, which increase the potassium levels in your blood (such as certain types of diuretics, potassium supplements, etc.).
- If you have porphyria.
- If you are taking a medicine called lithium.

- If you are treated with a blood pressure-lowering medicine containing aliskiren.
- If you have severe liver impairment.
- If you have severe low blood pressure (hypotension).
- If you have cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- If you suffer from heart failure after a heart attack.
- If you are pregnant or breastfeeding.

Warnings and precautions

Take special care with ZYVASC:

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

Contact your doctor to re-evaluate your treatment if you are treated with ACE inhibitors/angiotensin receptor blockers together with a fluoroquinolone antibiotic.

Your doctor may check your kidney function, blood pressure and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

Children and adolescents

The use of ZYVASC in children and adolescents is not recommended (aged below 18 years old).

Other medicines and ZYVASC

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

Tell your doctor if you are taking:

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

cyclooxygenase-2 inhibitors (COX-2 inhibitors). Your doctor may also check your kidney function.

ZYVASC with food and drink

Grapefruit and grapefruit juice should not be consumed by people who are taking ZYVASC. 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 ZYVASC.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ZYVASC.

Safety of ZYVASC in pregnant and breastfeeding women has not been established.

You should not use ZYVASC if you are pregnant, trying to become pregnant or breastfeeding your baby.

If you are a woman of childbearing age, you should ensure that you use effective contraception.

Driving and using machines

This medicine may make you feel dizzy. This can affect how well you can concentrate.

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

3. How to take ZYVASC

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

Always take ZYVASC exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of ZYVASC is one tablet per day.

- It is preferable to take your medicine at the same time each day.
- Swallow the tablets with a glass of water.
- You can take ZYVASC with or without food. Do not take ZYVASC with grapefruit or grapefruit juice.

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

Do not exceed the prescribed dose.

ZYVASC and older people (age 65 years or over)

Your doctor should exercise caution when increasing your dose.

If you take more ZYVASC than you should

Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may only develop later (24 – 48 hours after intake). You may stop breathing and need to be ventilated.

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

If you forget to take ZYVASC

Do not take a double dose to make up for forgotten individual doses.

If you stop taking ZYVASC

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

4. Possible side effects

ZYVASC can have side effects.

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

If any of the following happens, stop taking ZYVASC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZYVASC. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- sudden wheeziness, chest pain, shortness of breath or difficulty in breathing;
- severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of the mucous membranes (Stevens-Johnson syndrome, toxic epidermal necrolysis) or other allergic reactions;
- inflamed pancreas, which may cause severe abdominal and back pain accompanied with feeling of being very unwell;
- heart attack, abnormal heartbeat;
- upper airway swelling.

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

Tell your doctor if you notice any of the following:

Frequent side effects

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

Less frequent side effects

- loss of appetite;
- high calcium, sugar, cholesterol or uric acid levels in the blood;
- low levels of sodium in the blood;
- feeling anxious;
- abnormal coordination;
- drowsiness, tingling or numbness of the hands or feet;
- vision disturbance and impairment;
- ringing in the ears, head spinning;
- fast heartbeat including palpitations;
- low blood pressure and light-headedness when standing up;
- cough, sneezing/runny nose caused by inflammation of the lining of the nose (rhinitis);
- throat pain;
- constipation, change of bowel habit;
- diarrhoea, dry mouth;
- nausea, vomiting, indigestion;

- excessive sweating;
- redness of the skin;
- skin rash all over your body;
- joint swelling;
- back pain; pain in joints, muscle spasm, muscle cramps;
- sensation of heaviness;
- passing more urine than normal or feeling more of an urge to pass urine;
- inability to get or maintain an erection;
- a low level of white blood cells in the blood;
- low blood platelet count;
- excess sugar in blood (hyperglycaemia);
- mood changes, depression, confusion;
- taste abnormalities, loss of pain sensation, abnormal sensation, typically tingling or pricking ("pins and needles"), high level of muscle tone;
- trembling, sleeplessness, partial or total loss of sensation in a part of your body;
- an inflammation of the blood vessels that causes changes in the blood vessel walls;
- swelling of the gums;
- abdominal bloating (gastritis), increased liver enzymes which may have an effect on some medical tests;
- abnormal liver function, inflammation of the liver (hepatitis), yellowing of the skin (jaundice);
- hair loss;
- skin discolouration;
- skin sensitivity to light, purple spots under the skin, hives;
- discomfort or enlargement of the breasts in men;
- lack of energy;
- chest pain, feeling unwell;
- pain;
- weight increase or decrease.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of ZYVASC.

5. How to store ZYVASC

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the blister/carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ZYVASC contains

ZYVASC 5/160: Each film-coated tablet contains 6,9 mg amlodipine besilate (equivalent to 5 mg amlodipine) and 160 mg valsartan.

ZYVASC 10/160: Each film-coated tablet contains 13,9 mg amlodipine besilate (equivalent to 10 mg amlodipine) and 160 mg valsartan.

The other ingredients are colloidal anhydrous silica, crospovidone (E1201), magnesium stearate (E572), microcrystalline cellulose [E460(i)], Opadry Yellow [containing hypromellose (E464), iron oxide yellow (E172) (colourant), macrogol (E1521), polysorbate 80 (E433) and titanium dioxide (E171)].

What ZYVASC looks like and contents of the pack

ZYVASC 5/160: Dark yellow, oval, film-coated tablet, debossed “5” on one side and plain on other side.

ZYVASC 10/160: Light yellow, oval, film-coated tablet, debossed “10” on one side and plain on other side.

Silver aluminium/aluminium blister strips or PCV/Aclar/aluminium blister strips containing 15 tablets each, packed into an outer container.

Pack size: 30 film-coated tablets.

Holder of certificate of registration

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0157

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