

## PATIENT INFORMATION LEAFLET FOR VALDUO

### SCHEDULING STATUS S3

**VALDUO 5/80 film coated tablet**

**VALDUO 5/160 film coated tablet**

**VALDUO 10/160 film coated tablet**

**VALDUO 5/320 film coated tablet**

**VALDUO 10/320 film coated tablet**

Amlodipine besilate as amlodipine base and valsartan

VALDUO is sugar free

### Read all of this leaflet carefully before you start taking VALDUO

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

#### 1. What VALDUO is and what it is used for



VALDUO contains two active substances called amlodipine and valsartan. Both substances are used to treat high blood pressure.

- Amlodipine belongs to a group of substances called calcium channel blockers.
- Valsartan belongs to a group of substances called angiotensin receptor blockers (ARBs).

VALDUO is used to treat high blood pressure in adult patients whose blood pressure is not controlled with either amlodipine or valsartan on its own.

## 2. What you need to know before you take VALDUO:

### Do not take VALDUO if:

- You are hypersensitive (allergic) to amlodipine besilate, valsartan or any of the other ingredients of VALDUO listed in section 6.1.
- You have experienced swelling of the face and throat, while taking other medicines (including angiotensin receptor blockers (ARBs)).
- You have recurrent episodes of severe swelling without a known cause.
- Your doctor has told you that the thickness of your heart muscle is abnormal increased (obstructive hypertrophic cardiomyopathy (HOCM)) or that you have a narrowing of the valves in your heart (aortic or mitral stenosis).
- You have had a kidney transplant or if you have been told that you have a narrowing of your kidney arteries or if you have severe kidney problems/impairment.
- You have severe liver impairment.
- You have porphyria (a rare hereditary disease in which there is an abnormal metabolism of the blood pigment haemoglobin in your blood).
- You are pregnant or breastfeeding (see **Pregnancy, breastfeeding and fertility**).
- You have severe low blood pressure (hypotension)
- You have cardiogenic shock (a condition where your heart is unable to supply enough

blood to the body)

- You suffer from heart failure after a heart attack.
- You are using any of the following medicine (see **Other medicines and VALDUO**):
  - Renin inhibitors such as aliskiren (used to treat high blood pressure) if you have diabetes or impaired kidney function.
  - Lithium (used to treat some types of depression).
  - Potassium sparing diuretics such as spironolactone, triamterene, amiloride (water tablets).
  - Fluoroquinolones (antibiotics used to treat a variety of illnesses such as respiratory and urinary tract infections) if you have kidney problems or are elderly.

### **Warnings and precautions**

#### ***Take special care with VALDUO if:***

- You have kidney problems.
- You have liver problems.
- You have low blood pressure.
- You have been sick (vomiting) or have diarrhoea.
- 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.
- 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 VALDUO and contact your doctor straight away. You should never take VALDUO 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.

### **Children and adolescents**

The safety and efficacy of VALDUO has not been established in children (aged below 18 years old).

### **Other medicines and VALDUO**

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

In particular, tell your doctor if you are taking any of the following:

- Angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor blockers (ARBs) or renin inhibitors such as aliskiren (used to treat high blood pressure).
- Lithium (used to treat some types of depression).
- Potassium sparing diuretics such as spironolactone, triamterene, amiloride (used to remove excess fluid from your body).
- Potassium supplements, salt substitutes containing potassium and other substances that may increase potassium levels.
- Certain types of painkillers called non-steroidal anti-inflammatory drugs (NSAIDs, such as aspirin, diclofenac, ibuprofen) or selective cyclooxygenase-2 inhibitors (COX-2 inhibitors, such as rofecoxib, celecoxib).
- Anticonvulsant medicines (such as carbamazepine, phenobarbitone, phenytoin, fosphenytoin, primidone).
- St. John's wort (a herbal medicine used to treat depression).
- Medicines used for HIV/AIDS (such as ritonavir, indinavir, nelfinavir).
- Medicines used to treat fungal infections (such as ketoconazole, itraconazole).

- Medicines used to treat bacterial infections (such as rifampicin, erythromycin clarithromycin, telithromycin and fluoroquinolones such as ciprofloxacin, levofloxacin, moxifloxacin).
- Verapamil, diltiazem (heart medicines).
- Simvastatin (a medicine used to control high cholesterol levels).
- Dantrolene (infusion to treat 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).

### **Pregnancy, breastfeeding and fertility**

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

### **Women of childbearing potential/Contraception in males and females**

If you are a woman and old enough to be able to become pregnant, you should ensure that you use effective contraception.

### **Pregnancy**

Do not take VALDUO if you are pregnant or planning to become pregnant.

**If you become pregnant, stop taking VALDUO and call your doctor immediately. VALDUO can harm an unborn baby causing injury and even death. If you plan to become pregnant, talk to your doctor about other treatment options to lower your blood pressure before taking VALDUO.**

### **Breastfeeding**

Do not take VALDUO if you are breastfeeding.

### **Driving and using machines**

VALDUO may cause side effects, such as dizziness, drowsiness and visual disturbances and can affect your ability to drive a vehicle and use machines (see **Side effects**). Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how VALDUO affects you.

### **3. How to take VALDUO**

Do not share medicines prescribed for you with any other person

Always take VALDUO exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The usual dose is one tablet daily, at the same time each day. Take the tablet with some water.

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

Your doctor will tell you how long your treatment with VALDUO will last. Do not stop treatment early because your condition might worsen.

If you have the impression that the effect of VALDUO is too strong or too weak, tell your doctor or pharmacist.

### **If you take more VALDUO than you should**

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

Taking too many tablets may cause your blood pressure to become low or even dangerously low.

You may feel dizzy, 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. Excess fluid may

accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

### **If you forget to take VALDUO**

If you have missed your dose by only a few hours, take the missed dose as soon as you remember.

If it is almost time for your next dose, skip the missed dose and take VALDUO at the next regularly scheduled time. Do not take a double dose to make up for the forgotten individual doses.

### **If you stop taking VALDUO**

Your doctor will tell you how long to take VALDUO. Your condition may return if you stop taking VALDUO before you are advised.

## **4. Possible side effects**

VALDUO can have side effects.

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

If any of the following happens, stop taking VALDUO 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 reaction to VALDUO. 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.
- Heart attack, abnormal/irregular heartbeat, changes in the way your heart beats, for example, if you notice it beating faster
- Vasculitis which may include fever, headache, fatigue, weight loss, general aches and pains, night sweats, nerve problems such as numbness or weakness.
- Gastritis causing pain, nausea, vomiting, vomiting blood, blood in the stool.
- Inflamed pancreas, which may cause severe abdominal and back pain accompanied with feeling of being very unwell.
- Inflamed liver, which may include pain or bloating in the belly area, yellowing of the skin and eyes, also called jaundice, dark urine, and tiredness; liver problems
- Kidney failure which may include symptoms such as drowsiness, shortness of breath, tiredness, confusion, nausea, fits, passing less urine than is normal for you.
- Upper airway swelling (angioedema)

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:*

- Flu-like symptoms; nasal congestion,
- Sore throat and discomfort when swallowing,
- Low potassium levels in the body,
- Headache,

- Asthenia (weakness),
- Dizziness,
- Stomach pain,
- Feeling sick (nausea),
- Lack of energy,
- Facial swelling,
- Redness and warm feeling of the face and/or the neck,
- Swelling in the body caused by excess fluid. It often affects the lower body, such as the legs, feet, and ankle but it can occur anywhere.

*Less frequent side effects:*

- Decreased number of white blood cells which could increase the risk of infections, decreased number of platelets in your blood which could cause bleeding or bruising more Easily,
- Anorexia,
- Increase calcium levels in the body, increase in blood sugar levels, increase uric acid levels in the body, increase lipid levels in the body, decreased levels of sodium in the blood,
- Depression, anxiety, insomnia/sleep disturbances, mood swings, confusion,
- Abnormal coordination,
- Altered or impaired sense of taste,
- Muscle overactivity,
- Paraesthesia (Tingling or prickling sensation),
- Weakness, numbness and pain from nerve damage, usually in the hands and feet.
- Somnolence (sleepiness, feeling of drowsiness),
- Fainting, tremor, decreased sense of touch,
- Vision disturbance and impairment,
- Tinnitus (ringing in the ears),

- Vertigo (head spinning),
- 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, vomiting (being sick),  
indigestion, swelling of the gums,
- Increase in liver enzymes
- Hair loss, excessive sweating, redness of the skin, skin rash all over your body, skin  
discolouration, skin sensitivity to light, purple spots under the skin, hives
- 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, frequent urination  
at night,
- Inability to get or maintain an erection, erectile dysfunction, breast enlargement in men
- General feeling of discomfort, chest pain, pain,
- Weight increase or decrease.

*Side effects of unknown frequency:*

- Decreased red blood cells, or low levels of neutrophils when your blood is tested,
- Involuntary movements you cannot control,
- Inflammation of the skin with large, fluid-filled blisters,
- Increase in blood creatinine levels (usually indicate that the kidneys are not working as they  
should),
- High potassium levels in the blood.

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



### **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist.

You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications:

<https://www.sahpra.org.za/Publications/Index/8>.

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

### **5. How to store VALDUO**

Store all medicines out of reach of children.

Store at or below 30 °C.

Keep the blister strips in the outer carton until required for use.

Protect from moisture.

Do not use after the expiry date printed on the carton.

Return all unused tablets to your pharmacist.

Do not dispose of unused tablets in drains or sewerage systems (e.g. toilets).

### **6. Contents of the pack and other information**

#### ***What VALDUO contains***

The active substances of VALDUO are amlodipine besilate as amlodipine base and valsartan.

VALDUO 5/80: Each film coated tablet contains amlodipine besilate equivalent to 5 mg amlodipine base and 80 mg valsartan.

VALDUO 5/160: Each film coated tablet contains amlodipine besilate equivalent to 5 mg amlodipine base and 160 mg valsartan.

VALDUO 10/160: Each film coated tablet contains amlodipine besilate equivalent to 10 mg amlodipine base and 160 mg valsartan.

VALDUO 5/320: Each film coated tablet contains amlodipine besilate equivalent to 5 mg

amlodipine base and 320 mg valsartan.

VALDUO 10/320: Each film coated tablet contains amlodipine besilate equivalent to 10 mg amlodipine base and 320 mg valsartan.

The other ingredients are colloidal anhydrous silica, crospovidone, magnesium stearate, microcrystalline cellulose, Opadry Yellow (hypromellose, iron oxide yellow (colourant), macrogol, talc, titanium dioxide (colourant)).

VALDUO 5/160 and 5/320 also contains iron oxide red (colourant).

#### **What VALDUO looks like and contents of the pack**

VALDUO 5/80: Light yellow, round shaped, biconvex, film coated tablet, plain on both sides.

VALDUO 5/160: Dark yellow, oval shaped, biconvex, film coated tablet, debossed with 'L298' on one side and plain on the other side.

VALDUO 10/160: Light yellow, oval shaped, biconvex, film coated tablet, debossed with 'L300' on one side and plain on the other side.

VALDUO 5/320: Dark yellow, oval shaped, biconvex, film coated tablet, debossed with 'L299' on one side and plain on the other side.

VALDUO 10/320: Light yellow, oval shaped, biconvex, film coated tablet, debossed with 'L301' on one side and plain on the other side.

#### **Holder of certificate of registration**

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