PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

VALAZYD 40 mg film-coated tablets

VALAZYD 80 mg film-coated tablets

VALAZYD 160 mg film-coated tablets

Valsartan

Sugar free.

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- VALAZYD has been prescribed for you personally and you should not share the medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What VALAZYD is and what it is used for

VALAZYD contains the active ingredient valsartan. Valsartan belongs to a group of medicines called angiotensin II receptor antagonists or blockers (ARBs). Angiotensin II is a substance in the body that causes vessels to tighten, thus causing your blood pressure to increase. VALAZYD

works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

VALAZYD is used as treatment for the following in adults:

- high blood pressure;
- after a recent heart attack;
- heart failure.

2. What you need to know before you take VALAZYD

Do not take VALAZYD:

- If you are hypersensitive (allergic) to valsartan or any of the other ingredients of VALAZYD listed in section 6 of this leaflet.
- If you are pregnant or breastfeeding.
- If you have severe kidney impairment.
- If you have a history of angioedema (swelling around your face, throat or tongue) related to previous therapy with ARBs or angiotensin-converting enzyme inhibitors (ACEIs) (used to treat high blood pressure).
- If you have hereditary angioedema (swelling around your face, throat or tongue).
- If you have hypertrophic obstructive cardiomyopathy (HOCM) (a heart disease characterised by the obstruction of blood flow and thickening of heart tissue).
- If you have renal artery stenosis (kidney problems with reduced blood supply to your kidney).
- If you have aortic stenosis (a decrease in blood supply flow through the aortic artery).
- If you are taking potassium-sparing diuretics (such as spironolactone, triamterene or amiloride).
- If you have porphyria.
- If you are taking lithium.
- If you are being treated with a blood pressure-lowering medicine containing aliskiren.
- If you have kidney impairment or are over the age of 65 and are using fluoroquinolones (used to treat bacterial infections).

Warnings and precautions

Tell your doctor or health care provider before taking VALAZYD:

- If you experience excessive vomiting or diarrhoea (leading to salt/volume depletion).
- If you are on a salt-restricted diet.
- If you take diuretics (water pills) or potassium supplements.
- If you have been diagnosed with primary hyperaldosteronism (a hormone imbalance causing high blood pressure, low levels of potassium, feeling tired, headache, muscle weakness).
- If you suffer from kidney problems.
- If you suffer from liver problems.
- If you are taking medicines to lower blood pressure (such as an ACE inhibitor or aliskiren).
- If you have kidney problems resulting from diabetes.
- If you are 65 years or older.

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

Children and adolescents

Safety and efficacy of VALAZYD have not been established in children and adolescents under the age of 18 years and should therefore not be given to these patients.

Other medicines and VALAZYD

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

You may need to have your blood checked regularly if you take:

- Potassium supplements or medicines that may increase potassium levels in the blood (such as heparin).
- Nonsteroidal anti-inflammatory drugs (NSAIDs) (used to treat pain, fever and inflammation).

It is important to tell you doctor if you take:

- Other medicines to lower your blood pressure or medicines that may affect your blood pressure, such as renin-angiotensin-aldosterone system inhibitors (captopril, zofenopril), ACE inhibitors (enalapril, ramipril, fosinopril), or angiotensin II receptor blockers (losartan, candesartan, irbesartan).
- Medicines containing lithium.
- Fluoroquinolones (used to treat bacterial infections), such as levofloxacin, ciprofloxacin or moxifloxacin.
- Rifampicin (used to treat tuberculosis [TB]).
- Ciclosporin (used to prevent organ rejection after a transplant).
- Ritonavir (used in the treatment of HIV [human immunodeficiency virus] and AIDS [acquired immune deficiency syndrome]).

VALAZYD with food and drink

See section 3.

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 VALAZYD.

VALAZYD should not be used during pregnancy and breastfeeding.

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

Driving and using machines

VALAZYD may cause side effects, such as dizziness or weariness. Do not drive a vehicle or operate machinery until you know how VALAZYD affects you.

3. How to take VALAZYD

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

Always take VALAZYD exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

High blood pressure (hypertension)

The usual dose is 80 mg or 160 mg taken once a day.

Your doctor may prescribe VALAZYD with other medicines to control your blood pressure.

After a recent heart attack

The usual dose is 20 mg taken twice a day.

Your doctor may gradually increase your dose up to 160 mg taken twice daily, based on your condition.

Your doctor may prescribe VALAZYD with other medicines prescribed in the treatment following a heart attack.

Heart failure

The usual dose is 40 mg taken twice a day.

Your doctor may gradually increase your dose up to 160 mg taken twice daily, based on your condition.

All strengths of VALAZYD contain median lines and can be divided into equal halves.

VALAZYD can be taken with or without food.

Your doctor will tell you how long your treatment with VALAZYD will last. If you have the impression that the effect of VALAZYD is too strong or too weak, tell your doctor or pharmacist.

If you take more VALAZYD than you should

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre.

If you forget to take VALAZYD

If you forget to take a dose, take it as soon as you remember unless it is nearly time to take your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking VALAZYD

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

4. Possible side effects

VALAZYD can have side effects.

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

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

- swelling of your 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 VALAZYD. 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:

- heart failure (shortness of breath, fatigue and weakness, swelling in your legs, ankles and feet, persistent cough or wheezing with white or pink blood-tinged phlegm);
- kidney failure or impairment (drowsiness, shortness of breath, fatigue, confusion, nausea, fits,

passing less urine than is normal for you).

- bleeding or bruising more easily than normal;
- frequent infections such as fever, severe chills, sore throat or mouth ulcers;
- decreased levels of haemoglobin or percentage of red blood cells in the blood (weakness, dizziness, shortness of breath, pale skin, pounding in the ears, cold hands and feet, irregular heartbeat);
- too high levels of potassium in your blood (abnormal or slow heart rate, low blood pressure, cramps, weakness);
- vasculitis (fever, headache, fatigue, weight loss, general aches and pains, night sweats, nerve problems such as numbness or weakness).

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:

- infection caused by viruses;
- low blood pressure (dizziness or light-headedness);
- dizziness or light-headedness when getting up from a lying or sitting position, dizziness.

Less frequent side effects:

- upper respiratory tract infection (sneezing, cough, runny nose, scratchy or sore throat, fever);
- increases in blood levels of urea and creatinine (substances that measures kidney function),
- pharyngitis (runny nose, hoarseness, sore throat, dry cough), sinusitis (blocked nose, headache, pain and swelling around your cheeks, eyes and forehead) or rhinitis (runny nose);
- sleeplessness;
- decreased libido;
- vertigo (sensation of spinning or swaying);
- headache;
- cough;
- diarrhoea, pain in your stomach area, nausea (feeling sick);

- back pain, pain in a joint, pain in a muscle or group of muscles;
- feeling tired, abnormal physical weakness or lack of energy.

The following side effects have been reported with an unknown frequency:

- too low levels of sodium in your blood (nausea [feeling sick], vomiting [being sick], shortness of breath, headache, dizziness, confusion, convulsions [fits], coma);
- abnormal liver function tests.

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. 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 VALAZYD.

5. How to store VALAZYD

- Store at or below 25 °C.
- Protect from moisture.
- 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 carton or blister strips.
- 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 VALAZYD contains

The active substance in VALAZYD is valsartan.

VALAZYD 40: Each tablet contains 40 mg valsartan.

VALAZYD 80: Each tablet contains 80 mg valsartan.

VALAZYD 160: Each tablet contains 160 mg valsartan.

The other ingredients are calcium hydrogen phosphate (anhydrous), colloidal silica (anhydrous), crospovidone, hypromellose, iron oxide black (E172) (VALAZYD 40 and VALAZYD 160 only), iron oxide red (E172), iron oxide yellow (E172), magnesium stearate (E572), microcrystalline cellulose (E460a), polyethylene glycol and titanium dioxide (E171).

What VALAZYD looks like and contents of the pack

VALAZYD 40: Yellow coloured, oval shaped, bevelled edge, film-coated tablets with break line on one side and plain on the other side. The break line on one side of VALAZYD 40 is to divide the tablet into equal doses.

VALAZYD 80: Pink coloured, round shaped, bevelled edge, film-coated tablets with median line on one side and plain on the other side. The median line on one side of VALAZYD 80 is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

VALAZYD 160: Yellow coloured, oval shaped, bevelled edge, film-coated tablets debossed with median line on one side and plain on the other side. The median line on one side of VALAZYD 160 is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

Silver aluminium/aluminium foil blister strips placed in an outer carton.

Pack size: 30 tablets.

Holder of certificate of registration

Zydus Healthcare SA (Pty) Ltd

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