PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

VALAZYD CO 80/12,5 film-coated tablets

VALAZYD CO 160/12,5 film-coated tablets

VALAZYD CO 160/25 film-coated tablets

Valsartan and hydrochlorothiazide

Sugar free

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

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

1. What VALAZYD CO is and what it is used for

VALAZYD CO film-coated tablets contain two active substances called valsartan and hydrochlorothiazide.

Both of these substances help to control high blood pressure (hypertension).

- Valsartan belongs to a class of medicines known as “angiotensin II receptor antagonists”, which help to control high blood pressure. Angiotensin II is a substance in the body that causes vessels to tighten, thus causing your blood pressure to increase. Valsartan works by blocking the effect of angiotensin II. As a result, blood vessels relax, and blood pressure is lowered.
- Hydrochlorothiazide belongs to a group of medicines called thiazide diuretics (also known as “water tablets”). Hydrochlorothiazide increases urine output, which also lowers blood pressure.

VALAZYD CO is used to treat high blood pressure, which is not adequately controlled by a single substance alone.

2. What you need to know before you take VALAZYD CO

Do not take VALAZYD CO:

- If you are allergic (hypersensitive) to valsartan, hydrochlorothiazide or any of the other ingredients of VALAZYD CO (listed in section 6).
- If you have developed swelling of the face, lips, mouth, tongue or throat and giant wheals on your skin when previously taking medicines called angiotensin-converting enzyme (ACE) inhibitors or angiotensin receptor blockers (ARBs) – you should never take these medicines again.
- If you suffer from obstruction of blood vessels to your heart or kidneys.
- If you suffer from severe kidney function impairment.
- If you suffer from porphyria.
- If you are currently taking lithium.
- If you are currently taking potassium-sparing water tablets containing spironolactone, triamterene or amiloride.
- If you are taking fluoroquinolones (antibiotics to treat infections).

- If you are currently taking aliskiren-containing medicines.
- If you are pregnant or breastfeeding.
- If the level of potassium or sodium in your blood is lower than normal, or if the level of calcium in your blood is higher than normal despite treatment.
- If you have previously had or currently have cancer of the skin and/or lip.

Warnings and precautions

Should you become pregnant while receiving VALAZYD CO, your doctor should stop your treatment with VALAZYD CO and switch you to a different class of antihypertensive medicine (see “Do not take VALAZYD CO” and “Pregnancy, breastfeeding and fertility”).

Take special care with VALAZYD CO:

- If you are taking potassium-sparing medicines, potassium supplements, salt substitutes containing potassium or other medicines that increase the amount of potassium in your blood, such as heparin. Your doctor may need to check the amount of potassium in your blood regularly.
- If you have low levels of potassium in your blood.
- If you have diarrhoea or severe vomiting.
- If you are taking high doses of water tablets (diuretics).
- If you have severe heart disease.
- If you are suffering from heart failure or have experienced a heart attack. Follow your doctor’s instruction for the starting dose carefully. Your doctor may also check your kidney function.
- If you suffer from a narrowing of the kidney artery.
- If you have recently received a new kidney.
- If you suffer from hyperaldosteronism. This is a disease in which your adrenal glands make too much of the hormone aldosterone. If this applies to you, the use of VALAZYD CO is not recommended.

- If you have liver or kidney disease.
- If you have ever experienced swelling of the tongue and face caused by an allergic reaction, called angioedema, when taking another medicine (including ACE inhibitors), tell your doctor. If these symptoms occur when you are taking VALAZYD CO, stop taking VALAZYD CO immediately and never take it again. See also section 4, “Possible side effects”.
- If you have fever, rash and joint pain, which may be signs of systemic lupus erythematosus (SLE, an autoimmune disease).
- If you have diabetes, gout, high levels of cholesterol or triglycerides in your blood.
- If you have had allergic reactions with the use of other blood pressure-lowering medicines of this class (angiotensin II receptor antagonists) or if you have allergy or asthma.
- If you experience a decrease in vision or eye pain. These could be because of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking VALAZYD CO. This can lead to permanent vision loss, if not treated. If you have earlier had a penicillin or sulphonamide allergy you can be at higher risk of developing this.
- If you are taking any of the following medicines used to treat high blood pressure:
  - an ACE inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems
  - aliskiren.
- If you have had skin cancer or if you develop an unexpected skin lesion during the treatment.

Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and UV rays while taking VALAZYD CO.

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

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

See also information under the heading “Do not take VALAZYD CO”.

VALAZYD CO may cause increased sensitivity of the skin to the sun.

Children and adolescents

The use of VALAZYD CO in children and adolescents (below the age of 18 years) is not recommended.

Other medicines and VALAZYD CO

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

The effect of the treatment can be influenced if VALAZYD CO is taken together with certain other medicines. It may be necessary to change the dose, to take other precautions, or in some cases to stop taking one of the medicines. This especially applies to the following medicines:

- Lithium, a medicine used to treat some types of psychiatric diseases.
- Medicines or substances that may increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin.
- Medicines that may reduce the amount of potassium in your blood, such as diuretics (water tablets), corticosteroids, laxatives, carbenoxolone, amphotericin or penicillin G.
- Some antibiotics (rifamycin group), a medicine used to protect against transplant rejection (ciclosporin) or an antiretroviral medicine used to treat human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS) (ritonavir). These medicines may increase the effect of VALAZYD CO.
- Medicines that may induce “torsades de pointes” (irregular heartbeat), such as antidysrhythmics (medicines used to treat heart problems) and some antipsychotics.

- Medicines that may reduce the amount of sodium in your blood, such as antidepressants, antipsychotics, antiepileptics.
- Medicines for the treatment of gout, such as allopurinol, probenecid, sulfinpyrazone.
- Therapeutic vitamin D and calcium supplements.
- Medicines for the treatment of diabetes (oral medicines such as metformin or insulins).
- Other medicines to lower your blood pressure including methyldopa, ACE inhibitors (such as enalapril, lisinopril) or aliskiren (see also information under the headings “Do not take VALAZYD CO” and “Warnings and precautions”).
- Medicines to increase blood pressure, such as noradrenaline or adrenaline.
- Digoxin or other digitalis glycosides (medicines used to treat heart problems).
- Medicines that may increase blood sugar levels, such as diazoxide or beta blockers.
- Cytotoxic medicines (used to treat cancer), such as methotrexate or cyclophosphamide.
- Pain killers such as nonsteroidal anti-inflammatory drugs (NSAIDs), including selective cyclo-oxygenase-2 inhibitors (Cox-2 inhibitors) and acetylsalicylic acid (aspirin) > 3 g.
- Muscle relaxing medicines, such as tubocurarine.
- Anticholinergic medicines (medicines used to treat a variety of disorders such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, Parkinson's disease and as an aid to anaesthesia).
- Amantadine (medicine used to treat Parkinson’s disease and also used to treat or prevent certain illnesses caused by viruses).
- Colestyramine and colestipol (medicines used mainly to treat high levels of lipids in the blood).
- Alcohol, sleeping pills and anaesthetics (medicines with sleeping or painkilling effects, used for example during surgery).
- Iodine contrast media (agents used for imaging examinations).

VALAZYD CO with food and drink

Avoid drinking alcohol as alcohol may make your blood pressure fall more and/or increase the risk of you becoming dizzy or feeling faint.

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 taking VALAZYD CO.

Do not take VALAZYD CO if you are pregnant, are considering becoming pregnant or are breastfeeding.
If you are a woman of childbearing age, you must use effective contraception.

Driving and using machines

Before you drive a vehicle, use tools or operate machines or carry out other activities that require concentration, make sure you know how VALAZYD CO affects you. Like many other medicines used to treat high blood pressure, VALAZYD CO may occasionally cause dizziness and affect the ability to concentrate.

3. How to take VALAZYD CO

Do not share medicines prescribed for you with any other person.
Always take VALAZYD CO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you exactly how many tablets of VALAZYD CO to take. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

- The recommended dose of VALAZYD CO is one tablet per day.
- Do not change the dose or stop taking the tablets without consulting your doctor.
- VALAZYD CO should be taken at the same time each day, usually in the morning.
- You can take VALAZYD CO with or without food.

- Swallow the tablet with a glass of water.

VALAZYD CO tablets are only for adults and should not be taken by children and adolescents up to 18 years. If you have the impression that VALAZYD CO is too strong or too weak, tell your doctor or pharmacist.

If you take more VALAZYD CO than you should

If you experience severe dizziness and/or fainting, contact your doctor immediately and lie down. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take VALAZYD CO

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with VALAZYD CO is stopped

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

4. Possible side effects

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

If any of the following happens, stop taking VALAZYD CO 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 CO. You may need urgent medical attention or hospitalisation.

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

- severe skin disease that causes rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (toxic epidermal necrolysis),
- decrease in vision or pain in your eyes due to high pressure (possible signs of acute angle closure glaucoma),
- fever, sore throat, more frequent infections (agranulocytosis).

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

Tell your doctor if you notice any of the following:

Frequent:

- low level of potassium in the blood,
- increase of lipids in the blood,
- low level of sodium in the blood,
- low level of magnesium in the blood,
- high level of uric acid in the blood,
- itchy rash and other types of rashes,
- reduced appetite,
- mild nausea and vomiting,
- dizziness, fainting on standing up,
- inability to achieve or maintain an erection.

Less frequent:

- cough,
- low blood pressure,
- light-headedness,
- dehydration (with symptoms of thirst, dry mouth and tongue, infrequent urination, dark coloured urine, dry skin),
- muscle pain,
- tiredness,
- tingling or numbness,
- blurred/impaired vision,
- noises (e.g. hissing, buzzing) in ears,
- diarrhoea,
- joint pain,
- spinning sensation,
- abdominal pain,
- swelling and blistering of the skin (due to increased sensitivity to sun),
- high level of calcium in the blood,
- high level of sugar in the blood,
- sugar in the urine,
- worsening of diabetic metabolic state,
- constipation, diarrhoea, discomfort of the stomach or bowels, liver disorders which can occur together with yellow skin and eyes,
- irregular heartbeat,
- headache,
- sleep disturbances,
- sad mood (depression),
- low level of blood platelets (sometimes with bleeding or bruising underneath the skin),

- inflammation of blood vessels with symptoms such as rash, purplish-red spots, fever (vasculitis),
- rash, itching, hives, difficulty breathing or swallowing, dizziness (hypersensitivity reactions),
- facial rash, joint pain, muscle disorder, fever (lupus erythematosus),
- severe upper stomach pain (pancreatitis),
- difficulty breathing with fever, wheezing, breathlessness (respiratory distress including pneumonitis and pulmonary oedema),
- pale skin, tiredness, breathlessness, dark urine (haemolytic anaemia),
- fever, sore throat or mouth ulcers due to infections (leucopenia),
- confusion, tiredness, muscle twitching and spasm, rapid breathing (hypochloraemic alkalosis).

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, pharmacist or nurse. 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 CO.

5. How to store VALAZYD CO

- Store at or below 30 °C.
- Keep the blister strip(s) 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.
- 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 CO contains

The active substances in VALAZYD CO are valsartan and hydrochlorothiazide.

VALAZYD CO 80/12,5: Each film-coated tablet contains 80 mg valsartan and 12,5 mg hydrochlorothiazide.

VALAZYD CO 160/12,5: Each film-coated tablet contains 160 mg valsartan and 12,5 mg hydrochlorothiazide.

VALAZYD CO 160/25: Each film-coated tablet contains 160 mg valsartan and 25 mg hydrochlorothiazide.

The other ingredients are crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, silica (colloidal, anhydrous).

Film coating:

VALAZYD CO 80/12,5:

Opadry Pink (containing hypromellose, iron oxide red and yellow [colourants], macrogol, talc, titanium dioxide).

VALAZYD CO 160/12,5 and VALAZYD CO 160/25:

Opadry Brown (containing hypromellose, iron oxide black, red and yellow [colourants], macrogol, talc, titanium dioxide).

What VALAZYD CO looks like and contents of the pack

VALAZYD CO 80/12,5: Pink coloured, oval shaped, biconvex, bevelled edge film-coated tablets, plain on both sides.

VALAZYD CO 160/12,5: Brownish red coloured, oval shaped, biconvex, bevelled edge film-coated tablets, plain on both sides.

VALAZYD CO 160/25: Brown coloured, oval shaped, biconvex, bevelled edge film-coated tablets

debossed with '25' on one side and plain on the other side.

VALAZYD CO is packed in silver aluminium OPA/Al/PVC blister strips containing 7, 10 or 14 tablets each.

Pack size: 28 or 30 tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration

Zydus Healthcare S.A. (Pty) Ltd

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