PROPOSED CLEAN PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

VALGEN CO 80/12,5 mg, film-coated tablets

VALGEN CO 160/12,5 mg, film-coated tablets

VALGEN CO 160/25 mg, film-coated tablets

VALGEN CO 320/12,5 mg, film-coated tablets

VALGEN CO 320/25 mg, film-coated tablets

Valsartan and Hydrochlorothiazide

Contains sugar: lactose monohydrate

Read all of this leaflet carefully before you start taking VALGEN CO

- 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.
- VALGEN 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 VALGEN CO is and what it is used for

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

Both of these active 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.

VALGEN 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 VALGEN CO

- **Do not take VALGEN CO:**

- if you are allergic (hypersensitive) to valsartan, hydrochlorothiazide or any of the other ingredients of VALGEN 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

Take special care with VALGEN 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 VALGEN 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 drug (including ACE inhibitors), tell your doctor. If these symptoms occur when you are taking VALGEN CO, stop taking VALGEN 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, a so-called 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 agents 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 symptoms of an increase of pressure in your eye and can happen within hours to a week of taking VALGEN CO. This can lead to permanent vision loss, if not treated. If you earlier have 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 inhibitors (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 VALGEN CO.
- if you experienced breathing or lung problems (including inflammation or fluid in the lungs) following hydrochlorothiazide intake in the past. If you develop any severe shortness of breath or difficulty breathing after taking VALGEN CO, seek medical attention immediately.

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.

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

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

Children/ and adolescents

The use of VALGEN CO in children is not recommended as safety and efficacy have not been established.

Other medicines and VALGEN 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 VALGEN 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 HIV/AIDS infection (ritonavir). These medicines may increase the effect of VALGEN CO.
- medicines that may induce “torsades de pointes” (irregular heart beat), such as antiarrhythmics (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 agents such as metformin or insulins).

- other medicines to lower your blood pressure including methyldopa, ACE inhibitors (such as enalapril, lisinopril, etc.) or aliskiren (see also information under the headings “Do not take VALGEN 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 non-steroidal anti-inflammatory drugs (NSAIDs), including selective cyclo-oxygenase-2 inhibitors (Cox-2 inhibitors) and acetylsalicylic acid > 3 g.
- muscle relaxing medicines, such as tubocurarine.
- anti-cholinergic 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).
- cholestyramine and colestipol (medicines used mainly to treat high levels of lipids in the blood).
- ciclosporin, a medicine used for organ transplant to avoid organ rejection.
- alcohol, sleeping pills and anaesthetics (medicines with sleeping or painkilling effect used for example during surgery).
- iodine contrast media (agents used for imaging examinations).

VALGEN CO with food and drink

VALGEN CO may be taken with or without food. 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, ask your doctor or pharmacist for advice before taking VALGEN CO.

Do not take VALGEN 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 VALGEN CO affects you. Like many other medicines used to treat high blood pressure, VALGEN CO may occasionally cause dizziness and affect the ability to concentrate.

VALGEN CO contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking VALGEN CO.

3. How to take VALGEN CO

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

Always take VALGEN CO exactly as your doctor has told you. Check with your doctor if you are not sure.

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

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

VALGEN CO tablets are only for adults.

If you have the impression that VALGEN CO is too strong or too weak, talk to your doctor or pharmacist.

If you take more VALGEN 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 VALGEN 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 a forgotten dose.

Effects when treatment with VALGEN CO is stopped:

Stopping your treatment with VALGEN 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

VALGEN CO can have side effects.

Not all side effects reported for VALGEN CO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VALGEN CO, please consult your doctor, pharmacist or other healthcare professional for advice.

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

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

These are all very serious side effects. If you have them, you may have had a serious reaction to VALGEN 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 angleclosure glaucoma),
- fever, sore throat, more frequent infections (agranulocytosis),
- severe shortness of breath, fever, weakness, and confusion (acute respiratory distress syndrome).

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 rash,
- reduced appetite,
- mild nausea and vomiting,
- dizziness, fainting on standing up,

- inability to achieve or maintain erection.

Less frequent:

- cough,
- low blood pressure,
- light-headedness,
- dehydration (with symptoms of thirst, dry mouth and tongue, infrequent urination, dark colored urine, dry skin),
- muscle pain,
- tiredness,
- tingling or numbness,
- blurred vision,
- noises (e.g. hissing, buzzing) in ears,
- dizziness,
- 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),
- vision disorder,
- 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).

Not known:

- breathing difficulty,
- severely decreased urine output,
- low level of sodium in the blood (which can trigger tiredness, confusion, muscle twitching and / or convulsions in severe cases),

- low level of potassium in the blood (sometimes with muscle weakness, muscle spasms, abnormal heart rhythm),
- low level of white cells in the blood (with symptoms such as fever, skin infections, sore throat or mouth ulcers due to infections, weakness),
- the level of bilirubin increased in blood (which can, in severe cases, trigger yellow skin and eyes),
- the level of blood urea nitrogen and creatinine increased in blood (which can indicate abnormal kidney function),
- the level of uric acid in blood increased (which can, in severe cases, trigger gout),
- syncope (fainting),
- blistering skin (sign of dermatitis bullous),
- skin rash with or without itching together with some of the following signs or symptoms: fever, joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms,
- rash, purplished-red spots, fever, itching (symptoms of inflammation of blood vessels),
- low level of blood platelets (sometimes with unusual bleeding or bruising),
- high level of potassium in the blood (sometimes with muscle spasms, abnormal heart rhythm),
- allergic reactions (with symptoms such as rash, itching, hives, difficulty breathing or swallowing, dizziness),
- swelling mainly of the face and throat; rash; itching,
- elevation of liver function values,
- the level of haemoglobin decreased and the percentage of red cells decreased in the blood (which both can, in severe cases, trigger an anaemia),
- kidney failure,
- low level of sodium in the blood (which can trigger tiredness, confusion, muscle twitching and/or convulsions in severe cases),
- weakness, bruising and frequent infections (aplastic anemia),

- severely decreased urine output (possible signs of renal disorder or renal failure),
- rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (possible signs of erythema multiforme),
- muscle spasm,
- fever (pyrexia),
- weakness (asthenia),
- skin and lip cancer (non-melanoma skin cancer).

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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

5. How to store VALGEN CO

- Store all medicines out of reach of children.
- Store at or below 25 ˚C in a dry place.
- Protect from moisture.
- Keep container tightly closed.
- Keep blister in the carton until required for use.
- Do not use after the expiry date stated on the carton / label.
- Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What VALGEN CO contains

The active substances are valsartan and hydrochlorothiazide.

VALGEN CO 80/12,5 mg tablet: Each tablet contains 80 mg valsartan and 12,5 mg hydrochlorothiazide. Contains sugar: lactose monohydrate 51,95 mg/tablet.

VALGEN CO 160/12,5 mg tablet: Each tablet contains 160 mg valsartan and 12,5 mg hydrochlorothiazide. Contains sugar: lactose monohydrate 103,90 mg/tablet.

VALGEN CO 160/25 mg tablet: Each tablet contains 160 mg valsartan and 25 mg hydrochlorothiazide. Contains sugar: lactose monohydrate 103,90 mg/tablet.

VALGEN CO 320/12,5 mg tablet: Each tablet contains 320 mg valsartan and 12,5 mg hydrochlorothiazide. Contains sugar: lactose monohydrate 207,80 mg/tablet.

VALGEN CO 320/25 mg tablet: Each tablet contains 320 mg valsartan and 25 mg hydrochlorothiazide. Contains sugar: lactose monohydrate 207,80 mg/tablet.

The other ingredients are**:**

Tablet core:

Cellulose microcrystalline,

Crospovidone,

Lactose monohydrate,

Magnesium stearate,

Povidone,

Silica, colloidal anhydrous,

Starch pregelatinized,

Stear-o-wet M [magnesium stearate/sodium lauryl sulphate].

Coating:

Opadry pink 03F84793 [HPMC 2910/Hypromellose 6 cP; titanium dioxide, macrogol/PEG 8000, talc, iron oxide yellow, iron oxide red].

Opadry pink 03F84782 [HPMC 2910/Hypromellose 5 cP, titanium dioxide, macrogol/PEG 4000, talc, iron oxide red, iron oxide black].

Opadry brown 03B57310 [HPMC 2910/Hypromellose 6 cP, titanium dioxide, macrogol/PEG 400, talc, iron oxide red].

Opadry brown 03F86873 [HPMC 2910/Hypromellose 6 cP, titanium dioxide, iron oxide yellow, macrogol/PEG 8000, iron oxide red, iron oxide black].

Opadry yellow 03F82965 [HPMC 2910/Hypromellose 6 cP, titanium dioxide, macrogol/PEG 8000, iron oxide yellow].

What VALGEN CO looks like and contents of the pack

VALGEN CO 80/12,5 mg: A light orange, film-coated, oval, biconvex tablet debossed with VH1 on one side of the tablet and M on the other side.

VALGEN CO 160/12,5 mg: A reddish, film-coated, oval, biconvex tablet debossed with VH2 on one side of the tablet and M on the other side.

VALGEN CO 160/25 mg: A brown, film-coated, oval, biconvex tablet, debossed with VH3 on one side of the tablet and M on the other side.

VALGEN CO 320/12,5 mg: A pink, film-coated, oval, biconvex tablet, debossed with VH4 on one side of the tablet and M on the other side.

VALGEN CO 320/25 mg: A yellow, film-coated, oval, biconvex tablet, debossed with VH5 on one side of the tablet and M on the other side.

Contents of the pack:

VALGEN CO is presented in the following pack types:

- HDPE bottle packs comprising of round wide mouth white HDPE bottles with opaque screw caps with induction sealing liners. The HDPE bottle packs may either be placed in an outer cardboard carton or provided without a carton based on commercial requirement.
- Cold form blister packs comprise of cold form laminate (aluminium foil laminated to oriented polyamide on one side and to PVC on the other side i.e. OPA/Al/PVC) on one side and hard tempered aluminium foil coated with heat seal lacquer on the other side. Suitable number of blister strips will be placed in an outer cardboard carton along with leaflet. The number of tablets per strip and the number of strips in each carton shall be based on commercial requirement.

Holder of Certificate of Registration

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1.3.2 Patient Information Leaflet

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