

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS S3****VALGEN 40 mg Film-coated tablets****VALGEN 80 mg Film-coated tablets****VALGEN 160 mg Film-coated tablets****VALGEN 320 mg Film-coated tablets**

Valsartan

Sugar free

Read all of this leaflet carefully before you start taking VALGEN

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

1. What VALGEN is and what it is used for

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

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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.

VALGEN can be used for three different conditions:

- To treat mild to moderate high blood pressure in adults.
- To treat adult patients after a recent heart attack (myocardial infarction).
- To treat symptomatic heart failure in adult patients.

2. What you need to know before you take VALGEN

Do not take VALGEN:

- if you are hypersensitive (allergic) to valsartan or any of the other ingredients of VALGEN (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 severe liver disease or biliary obstruction (a problem with the drainage of the bile from the gall bladder).
- 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 have a history of angioedema.
- if you have a heart condition called "hypertrophic obstructive cardiomyopathy" where the cardiac muscle is abnormally thickened and, during the contraction, it obstructs the blood flow in the left lower cavity of the heart.
- 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 (especially if you have Type 2 diabetes and/or kidney problems).

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- if you are pregnant or breastfeeding.

Warnings and precautions

Take special care with VALGEN:

- if you have liver disease.
- if you have severe kidney disease or if you are undergoing dialysis.
- if you are suffering from a narrowing of the kidney artery.
- if you have recently undergone kidney transplantation (received a new kidney).
- if you are treated after a heart attack or for heart failure, your doctor may check your kidney function.
- if you have severe heart disease other than heart failure or heart attack.
- if you are taking medicines that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin. It may be necessary to check the amount of potassium in your blood at regular intervals.
- if you suffer from aldosteronism. 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 is not recommended.
- if you have lost a lot of fluid (dehydration) caused by diarrhoea, vomiting, or high doses of water pills (diuretics).
- 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 VALGEN, stop taking VALGEN immediately and never take it again. See section 4 'Possible side effects'.
- 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 are being treated with an ACE-inhibitor together with certain other medicines to treat your heart failure, which are known as mineralocorticoid receptors antagonists (MRA) (for example spironolactone, eplerenone) or beta-blockers (for example metoprolol).

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 safety and efficacy of VALGEN have not been established in children.

Other medicines and VALGEN

Always tell your healthcare 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 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 applies to both prescription and non-prescription medicines, especially:

- other medicines that lower blood pressure, especially water tablets (diuretics).
- medicines that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin.
- certain type of pain killers called non-steroidal anti-inflammatory medicines (NSAIDs).
- fluoroquinolones (antibiotic used to treat bacterial infections).
- lithium, a medicine used to treat some types of psychiatric illness.
- 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.

In addition:

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- if you are being treated after a heart attack, a combination with ACE inhibitors (a medicine to treat heart attack) is not recommended.

Your doctor may need to change your dose and/or to take other precautions:

- if you are taking an ACE-inhibitor or aliskiren (see also information under the headings 'Do not take VALGEN and 'Warnings and precautions').
- if you are being treated with an ACE-inhibitor together with certain other medicines to treat your heart failure, which are known as mineralocorticoid receptors antagonists (MRA) (for example spironolactone, eplerenone) or beta-blockers (for example metoprolol).

VALGEN with food and drink

You can take VALGEN tablets with or without food. Swallow VALGEN tablets with a glass of water.

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 healthcare provider for advice before taking this medicine.

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

3. How to take VALGEN

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

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

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High blood pressure: The usual starting dose is 80 mg of VALGEN once daily. In some cases your doctor may prescribe higher doses (the dose can be increased to 160 mg and to a maximum of 320 mg). VALGEN may also be administered with other medicines for high blood pressure.

Adult patients after a recent heart attack: After a heart attack the treatment is generally started as early as after 12 hours, usually at a low dose of 20 mg twice daily. You obtain the 20 mg dose by dividing the 40 mg tablet. Your doctor will increase this dose gradually over several weeks to a maximum of 160 mg twice daily. The final dose depends on what you as an individual patient can tolerate.

VALGEN can be given together with other treatment for heart attack, and your doctor will decide which treatment is suitable for you.

Adult patients with heart failure: Treatment starts generally with 40 mg twice daily. Your doctor will increase the dose gradually over several weeks to a maximum of 160 mg twice daily. The final dose depends on what you as an individual patient can tolerate. VALGEN can be given together with other treatment for heart failure, and your doctor will decide which treatment is suitable for you.

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

VALGEN tablets are only for adults and should not be taken by children and adolescents up to 18 years.

If you take more VALGEN 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

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 is stopped:

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

4. Possible side effects

VALGEN can have side effects.

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

If any of the following happens, stop taking VALGEN 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. 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:

- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure);
- severe blistering of the skin (bullous dermatitis).

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

Tell your doctor if you notice any of the following:

Frequent:

- viral infections,
- dizziness,
- low blood pressure with or without symptoms such as dizziness and fainting when standing up,
- decreased kidney function (signs of renal impairment).

Less frequent:

- sudden loss of consciousness (syncope),
- spinning sensation (vertigo),
- severely decreased kidney function (signs of acute renal failure),
- increase of level of serum creatinine (which can indicate abnormal kidney function),
- muscle spasms, abnormal heart rhythm (signs of hyperkalaemia),
- swelling under the skin (angioedema),
- back pain, headache, cough, sore throat, hay fever, inflamed sinuses,
- abdominal pain, nausea, diarrhoea,
- tiredness, weakness,
- sleeplessness,
- low sex drive.

Unknown frequency:

- allergic reactions with rash, itching and hives; symptoms of fever, swollen joints and joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms may occur (signs of serum sickness),
- purplish-red spots, fever, itching (signs of inflammation of blood vessels also called vasculitis),
- unusual bleeding or bruising (signs of thrombocytopenia),
- muscle pain (myalgia),
- fever, sore throat or mouth ulcers due to infections (symptoms of low level of white blood cells also called neutropenia),
- decrease of level of haemoglobin and decrease of the percentage of red blood cells in the blood (which can lead to anaemia in severe cases),
- increase of level of potassium in the blood (which can trigger muscle spasms, abnormal heart rhythm in severe cases),
- elevation of liver function values (which can indicate liver damage) including an increase of bilirubin in the blood (which can trigger yellow skin and eyes in severe cases),
- increase of level of blood urea nitrogen (which can indicate abnormal kidney function),

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- low level of sodium in the blood (which can trigger tiredness, confusion, muscle twitching and/or convulsions in severe cases).

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.

5. How to store VALGEN

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 contains

The active substance is valsartan.

Each film-coated tablet contains 40 mg, 80 mg, 160 or 320 mg of valsartan.

Sugar free.

The other ingredients are:

Tablet core

Croscarmellose sodium

Crospovidone

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Magnesium stearate

Microcrystalline cellulose

Povidone K-30

Silica, colloidal anhydrous

Tablet coating

Hypromellose

Titanium dioxide

Macrogol/PEG 8000

Iron oxide yellow

Iron oxide black [40, 160 and 320 mg tablets]

Iron oxide red [80, 160 and 320 mg tablets]

What VALGEN looks like and contents of the pack

VALGEN 40 mg: Yellow, oval shaped, biconvex, film-coated tablets debossed with “VN” and “1” on either side of the score line on one side and “M” on the other side.

The tablet can be divided into equal doses.

VALGEN 80 mg: Pale red, round, biconvex, bevelled edged film-coated tablets having a score line on one side and debossed with “M” over “VN2” on other side.

The tablet can be divided into equal doses.

VALGEN 160 mg: Beige, oval-shaped, biconvex, bevelled-edge, film-coated tablets debossed with “M” to the left of the score on one side and “VN3” on the other side of the tablet.

The tablet can be divided into equal doses.

VALGEN 320 mg: Dark grey, oval-shaped, biconvex, film-coated tablets debossed with “VN4” on one side and “M” on the other side.

Contents of the pack:

28's or 30's HDPE bottle packs or cold form blister packs.

HDPE bottle pack comprising of white HDPE bottle with white opaque polypropylene closure with induction sealing liner. The HDPE bottle pack may either be placed in an outer cardboard carton or provided without

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a carton, based on commercial requirement. In case the HDPE bottle pack is not supplied in an outer carton, the leaflet shall be placed as an outsert.

Cold form blister pack comprising 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. 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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