

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

VASOVAN 40 film coated tablet

VASOVAN 80 film coated tablet

VASOVAN 160 film coated tablet

Each **VASOVAN 40** film coated tablet contains 40 mg valsartan. Contains sugar: anhydrous lactose 51,25 mg

Each **VASOVAN 80** film coated tablet contains 80 mg valsartan. Contains sugar: anhydrous lactose 102,50 mg

Each **VASOVAN 160** film coated tablet contains 160 mg valsartan. Contains sugar: anhydrous lactose 205,00 mg

Read all of this leaflet carefully before you start taking VASOVAN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or, pharmacist, nurse or other health care provider.
- **VASOVAN** 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 VASOVAN is and what it is used for
2. What you need to know before you take VASOVAN

3. How to take VASOVAN
4. Possible side effects
5. How to store VASOVAN
6. Contents of the pack and other information

1. What VASOVAN is and what it is used for

VASOVAN belongs to a class of medicines known as angiotensin-II receptor antagonists, which help to control high blood pressure.

- **VASOVAN** is used to treat high blood pressure. Due to narrowed arteries high blood pressure increases your heart's workload. If it continues for a long time, it can damage the blood vessels of the brain, heart, and kidneys, and may result in a stroke, heart failure, or kidney failure. High blood pressure increases the risk of heart attacks. Lowering your blood pressure to normal reduces the risk of developing these disorders.
- **VASOVAN** is used to treat adult heart failure patients. Heart failure is associated with shortness of breath, and swelling of the feet and legs due to fluid build-up. Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body.
- **VASOVAN** can also be used to treat adults after a heart attack (myocardial infarction) to improve survival and reduce further heart problems.

Angiotensin II is a natural substance in the body that causes blood vessels to tighten, thus causing your blood pressure to increase. **VASOVAN** works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

If you have any question about how **VASOVAN** works or why this medicine has been prescribed for you, ask your doctor.

2. What you need to know before you take VASOVAN

Do not take VASOVAN:

- If you are hypersensitive (allergic) to valsartan or any of the other ingredients of **VASOVAN** (see section 6).
- If you are pregnant or breastfeeding your baby (see section 2 - Pregnancy and breastfeeding and fertility).
- If you have a kidney disorder.
- If you have moderate or severe renal impairment (your kidneys are not functioning normally) and are also taking a fluoroquinolone (a class of antibiotic used to combat a bacterial infection) together with an angiotensin-converting enzyme (ACE) inhibitor (a class of heart medication) or a renin-angiotensin receptor blocker (such as **VASOVAN**) (see section 2 - Take special care with **VASOVAN**).
- If you have serious kidney impairment and are elderly, do not take **VASOVAN** with fluoroquinolones (see section 2 - Take special care with **VASOVAN**).
- If you have had angioedema (swelling of your face, lips, mouth, tongue or throat with or without difficulty in swallowing or breathing) while taking an angiotensin-converting enzyme inhibitor (ACE inhibitor) or an angiotensin receptor blocker, such as **VASOVAN**.
- If you have hypertrophic obstructive cardiomyopathy, a serious heart disorder where the muscles of the heart are thickened, interfering with normal blood flow.
- If you have narrowing of the blood vessels to both kidneys or to a single functioning kidney.
- If you have aortic stenosis, a narrowing of the aortic valve opening between the left ventricle (large pumping chamber of your heart) and the aorta (the main artery leading away from your heart).
- If you are taking diuretics (water tablets) such as spironolactone, triamterene or amiloride, that cause your body to retain potassium.
- If you have a condition called porphyria (a metabolic disorder).
- If you are taking lithium (used to treat some mood disorders).

- If you are using products containing aliskiren (used to treat high blood pressure).

Warnings and precautions

Take special care with VASOVAN:

- Low blood pressure (symptomatic hypotension) is likely to occur if you are dehydrated (excessive loss of body water) or have salt deficiency due to diuretic therapy (water tablets), low-salt diet, diarrhoea, or vomiting. The water and electrolyte balance in your body should be corrected before you start treatment with **VASOVAN**.
- 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 are treated with an ACE-inhibitor or aliskiren (hypertension pills)
- If you have a severe kidney disease or are undergoing dialysis
- Acute kidney failure (a serious condition resulting in your kidneys losing their function) may be caused by the simultaneous use of fluoroquinolones (a class of antibiotic that combats a bacterial infection) and an angiotensin-converting enzyme (ACE) inhibitor (a class of heart medication) or a renin-angiotensin receptor blocker (such as **VASOVAN**) (see section 2 - Do not take **VASOVAN**).
- If you ever had a swelling mainly of the face and throat while taking other drugs (including an ACE-inhibitor). If you get those symptoms, stop taking **VASOVAN** and contact your doctor immediately. You should never take **VASOVAN** again.
- Your doctor will assess your kidney function prior to starting simultaneous treatment with such medicines and will monitor your kidney function during treatment with fluoroquinolones (a class of antibiotic that combats a bacterial infection) and an ACE inhibitor (a class of heart medication) or a renin-angiotensin receptor blocker (such as **VASOVAN**) (see section 2 - Do not take **VASOVAN**).
- If you have a liver disorder where the bile flow is obstructed.

- If you have elevated potassium levels in your blood. Potassium-sparing diuretics should be avoided.
- If you are an elderly patient.

Children and adolescents

The safety and efficacy of **VASOVAN** has not been established in children and adolescents (below the age of 18 years).

Other medicines and VASOVAN

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently using:

- Fluoroquinolones (a class of antibiotic that combats a bacterial infection) (see section 2 - Take special care with **VASOVAN** and Do not take **VASOVAN**.)
- An angiotensin-converting enzyme (ACE) inhibitor (a class heart medication) (see section 2 - Take special care with **VASOVAN** and Do not take **VASOVAN**.)
- A renin-angiotensin receptor blocker (a class of heart medication) (see section 2 - Take special care with **VASOVAN** and Do not take **VASOVAN**.)
- Other medicines that lower blood pressure, especially water tablets (diuretics) or aliskiren.
- Medicines that increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium or potassium-sparing medicines. Your doctor may check the amount of potassium in your blood periodically.
- Lithium, a medicine used to treat some types of mood disorders.
- Nonsteroidal anti-inflammatory medicines (NSAIDs), e.g. aspirin or indomethacin. Your doctor may also check your kidney function

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Product Strength (and dosage form): 40mg /80 mg/ 160 mg (Film Coated Tablets)

- If you are being treated for heart failure, a triple combination with ACE inhibitors and beta blockers is not recommended.
- Some antibiotics (rifamycin group), a drug used to protect against transplant rejection (ciclosporin), or a medicine used to treat HIV/AIDS infection (ritonavir). These drugs may increase the effect of **VASOVAN**

If you are due to have an operation, tell the anaesthetist or the medical staff you are taking **VASOVAN** tablets.

VASOVAN with food and drink

VASOVAN can be taken with or without food.

Pregnancy and 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 professional for advice before taking **VASOVAN**.

DO NOT take **VASOVAN** tablets if you are pregnant, suspect that you are pregnant, or are planning to become pregnant.

DO NOT take **VASOVAN** tablets if you are breastfeeding your baby.

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

Driving and using machines

VASOVAN may cause dizziness and impair your ability to drive a vehicle or use machines.

Take special care before performing tasks requiring your attention, until you know how **VASOVAN** will affect you.

VASOVAN contains a sugar called, anhydrous lactose.

Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia or

glucose-galactose malabsorption should not take **VASOVAN**.

3. How to take VASOVAN

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

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

The usual dose is 40 mg, 80 mg or 160 mg once daily.

Your doctor may prescribe different doses, depending on your condition.

- For adults with high blood pressure, the usual dosage is one 80 mg or 160 mg tablet once a day. In some cases, your doctor may prescribe a higher dose (e.g. 320 mg tablet) or an additional medicine (e.g. a diuretic).
- In heart failure the treatment starts generally with 40 mg twice daily. The dose is gradually increased to 80 mg twice daily and 160 mg twice daily as tolerated by the patient.
- Following a heart attack, treatment is generally started as early as 12 hours, usually at a low dose of 20 mg twice daily. Your doctor will increase this dose gradually over several weeks to a maximum of 160 mg twice daily. Another formulation should be used for patients requiring a dose of 20 mg..

You should check with your doctor or pharmacist if you are unsure.

The tablets should be taken at about the same time each day.

Your doctor will tell you how long your treatment with VASOVAN will last. Do not stop treatment early because your disease may get worse.

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

Patients who have high blood pressure often do not notice any signs of this problem. Many may feel quite normal. This makes it all the more important for you to keep your appointments with the doctor even if you are feeling well. It is very important that you take

this medicine exactly as your doctor or pharmacist tells you in order to get the best results and reduce the risk of side effects.

VASOVAN is for oral use only.

If you take more VASOVAN than you should

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

Take this leaflet and the rest of the remaining **VASOVAN** tablets with you so the doctor will know what you have taken. You may experience severe dizziness and/or fainting as well as a slow or fast heartbeat.

If you forget to take VASOVAN

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 **VASOVAN** at the next regularly scheduled time. Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

VASOVAN can have side effects.

Not all side effects reported for **VASOVAN** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **VASOVAN**, please consult your doctor, pharmacist or other healthcare professional for advice.

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

- Angioedema (allergic reaction): Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, hives

- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **VASOVAN**. 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:

Side effects that may occur frequently:

- You frequently get infections due to a lack of white blood cells.
- Viral infections.

Side effects that may occur less frequently:

- allergic reaction with symptoms such as rash, itching, dizziness, swelling of face or lips or tongue or throat, difficulty breathing or swallowing (signs of angioedema)
- sudden loss of consciousness
- Your blood vessels get inflamed (vasculitis), heart problems, abnormal heart rhythm (signs of hyperkalemia)
- Swelling of your feet or legs (signs of cardiac failure) (oedema).
- Breathlessness, difficulty breathing when lying down, you get an infection in your airways.
- Diarrhoea, stomach pain, nausea (feeling sick), diarrhoea.
- Blurred vision.
- Muscle tenderness or weakness (myalgia), painful, swollen joints (arthralgia).
- You bleed or bruise more easily than normal due to a decreased number of platelets in your blood.
- You feel tired and look pale, because of a decreased number of red blood cells.
- Elevated levels of potassium in your blood.

There is a problem with the way your liver (increase of bilirubin in the blood (which can, in severe cases, trigger yellow skin and eyes) or kidneys work (increase of level of serum urea and increase level of serum creatinine).

Side effects occurring with unknown frequency:

- Liver disease with nausea, vomiting, fever, yellowing of the skin and whites of the eyes (hepatitis).

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

Tell your doctor as soon as possible if you notice any of the following:

Side effects that may occur frequently:

- Dizziness, light-headedness (especially when getting up from a lying or sitting position).
- Skin rash.

Side effects that may occur less frequently:

- Low blood pressure, problems sleeping.
- Cough, stuffy nose, inflammation of the sinuses, sore throat.
- Fatigue, unusual tiredness, decreased libido.
- Headache, a spinning feeling in your head.
- Elevated levels of potassium in your blood, elevated liver enzymes.

Side effects occurring with unknown frequency:

- Hair loss.
- blistering skin (sign of dermatitis bullous)
- rash, itching, together with some of the following signs or symptoms: swollen lymph nodes and/or flu-like symptoms (signs of serum sickness)
- purplish-red spots
- fever, sore throat or mouth ulcers due to infections (symptoms of low level of white blood cells also called neutropenia)

The frequency of some side effects may vary depending on your condition. For example, side effects such as dizziness, and decreased kidney function, were seen less frequently in adult patients treated with high blood pressure than in adult patients treated for heart failure or after a recent heart attack.

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 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.

Reporting can also be done directly to Unicorn Pharmaceuticals at:

vigilance@unicornpharma.co.za.

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

5. How to store VASOVAN

- Store at or below 25 °C.
- Keep blister strips in outer carton until required for use.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN.**
- 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 VASOVAN contains

The active ingredient: Each film coated tablet contains 40 mg, 80 mg and 160 mg valsartan respectively.

The other ingredients are anhydrous lactose, crospovidone, magnesium stearate,

microcrystalline cellulose, and silica.

VASOVAN 40 and **VASOVAN 160** also contain Opadry Yellow (consisting of hypromellose, macrogol, titanium dioxide and yellow iron oxide), and **VASOVAN 80** also contains Opadry Pink (consisting of hypromellose, macrogol, titanium dioxide, red iron oxide and yellow iron oxide).

Contains sugar (51,250 mg; 102,5 mg; 205,0 mg anhydrous lactose).

What VASOVAN looks like and contents of the pack

VASOVAN 40: Yellow coloured, round, biconvex, film coated tablets debossed with 'J' on one side and '40' on the other.

VASOVAN 80: Peach coloured, round, biconvex, film coated tablets, scored on one side and debossed with '80' on scored side and 'J' on the other.

VASOVAN 160: Yellow coloured, oval shaped, biconvex, film coated tablets, scored on one side and debossed with '160' on scored side and 'J' on the other.

2 x blister strips each containing 14 tablets are placed into a carton box (28 tablets per pack). The blister strips are comprised of aluminium foil and a multilayer base film (OPA/ aluminium foil/PVC).

Holder of Certificate of Registration

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Applicant: UNICORN PHARMACEUTICALS (PTY) LTD

Seq-0003-approved

Product Name: VASOVAN 40/ 80/ 160

Product Strength (and dosage form): 40mg /80 mg/ 160 mg (Film Coated Tablets)

Registration numbers

VASOVAN 40: 46/7.1.3/0950

VASOVAN 80: 46/7.1.3/0951

VASOVAN 160: 46/7.1.3/0952