

## **PACKAGE LEAFLET: Information for the patient**

### **VALSARTAN**

Film-coated tablets – 80 mg

(Valsartan)

#### **Read this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Valsartan is and what it is used for
2. Before you take Valsartan
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#### **1. WHAT VALSARTAN IS AND WHAT IT IS USED FOR**

Valsartan is an angiotensin II receptor antagonist. Angiotensin II, which is produced within the body, is a substance that causes the blood vessels to narrow. Valsartan prevents blood vessels from narrowing by blocking the effect of angiotensin II.

Valsartan 80 mg film-coated tablets are used for:

- *the treatment of hypertension*; high blood pressure increases the workload on the heart and arteries; if not treated 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;

- *the treatment of patients who have recently passed a heart attack (myocardial infarction);* “recent” here means from 12 hours to 10 days;
- *the treatment of patients with symptomatic heart failure,* when treatment with other specific medicines, known as ACE inhibitors (a medication to treat heart failure) cannot be used, or it may be used in addition to ACE-inhibitors, when other medications to treat heart failure cannot be used.

Heart failure symptoms include shortness of breath, and swelling of the feet and legs due to fluid build-up. It is caused when the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body.

Your doctor may have given Valsartan for another purpose. Ask your doctor if you want to know why you were given Valsartan.

## **2. BEFORE YOU TAKE VALSARTAN**

### **Do not take Valsartan if you:**

- are allergic (hypersensitive) to valsartan or any of the excipients of Valsartan;
- have a severe impairment of hepatic function or if you suffer from liver disease;
- are more than 3 months pregnant, (it is also better to avoid Valsartan in early pregnancy – see section “Pregnancy and breast-feeding”);
- have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

### **Take special care with Valsartan**

Ask your doctor before you take Valsartan:

- if you have a kidney disorder or if you are undergoing dialysis;
- if you have a liver disorder;
- if you are known to have a narrowing or obstruction in the blood vessels leading to your kidneys;
- if you have recently had a kidney transplant;
- if you suffer from hyperaldosteronism, a disorder in which the adrenal glands produce too much of a hormone known as aldosterone; if this applies to you, the use of Valsartan is not recommended;

- if you have severe vomiting or diarrhoea, as this may lead to heavy fluid and/or salt loss from your body;
- if you are being treated with diuretics (used to increase fluid excretion via the kidneys);
- if you are taking potassium-sparing medications or potassium preparations, if you use salt replacements containing potassium, or if you are using other medications (e.g. heparin), which increase the amount of potassium in your blood; it may be necessary to check the amount of potassium in your blood at regular intervals;
- if you have problems with your heart valves or heart muscle, or if you have any other severe heart disorder;
- if you are being treated for heart failure or after a heart attack, because your kidney function may worsen during treatment;
- 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 betablockers (for example metoprolol).

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 Valsartan if you”.

You must tell your doctor if you think that you are or might become pregnant. Valsartan is not recommended in early pregnancy (during the first months) and may cause serious harm to your baby after 3 months of pregnancy.

Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Valsartan. Your doctor will decide on further treatment. Do not stop taking Valsartan on your own.

## **Taking other medicines**

Concomitant treatment with other medicines may affect or be affected by Valsartan.

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

It may be necessary to change the dose, or in some cases to stop taking one of the medicines.

This applies to both prescription and non-prescription medicines.

Particular caution is advised if you take any of the following medicines during treatment with Valsartan:

- other medications to lower your blood pressure, especially diuretics, as these may lower your blood pressure even further;
- medicines that increase the amount of potassium in your blood, like potassium preparations, salt replacements containing potassium or potassium-sparing drugs such as certain diuretics, or other medicines that increase the amount of potassium in the blood (e.g. heparin);
- certain types of analgesics, called anti-inflammators (non-steroidal anti-inflammatory drugs); these medicines can make Valsartan less effective in lowering your blood pressure; if your kidney function is already impaired, taking these medicines at the same time as Valsartan can cause your kidney function to worsen;
- medicines containing lithium (medicine used to treat some types of psychiatric illness); you must not use Valsartan and lithium at the same time, unless you are being closely monitored by your doctor; in this case, the doctor may arrange for special precautions to be taken (e.g. blood tests);
- if you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Valsartan if you” and “Take special care with Valsartan”);
- 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 betablockers (for example metoprolol).

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

If you are being treated for heart failure, a triple combination with ACE inhibitors and beta-blockers (medications to treat heart failure) is not recommended.

### **Pregnancy and breastfeeding**

You must consult your doctor if you think that you are or might become pregnant. Your doctor will normally advise you to stop taking Valsartan before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Valsartan.

Valsartan is not recommended in the first months of pregnancy, and it should not be taken in the second and third trimester because it can cause serious harm to the fetus.

Consult your doctor if you are breastfeeding or about to start breastfeeding.

Valsartan is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you, especially if your baby was born prematurely (less than 9 months).

Ask your doctor or pharmacist for advice before taking any medicine.

### **Taking Valsartan with food and drink**

Valsartan can be taken with or without meals.

### **Driving and using machines**

Like many other medicines used to treat high blood pressure, Valsartan may in rare cases cause dizziness and affect the ability to concentrate. So before you drive a vehicle, use machinery, or carry out other activities that require concentration, make sure you know how you react to the effects of Valsartan.

## **3. HOW TO TAKE VALSARTAN**

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

People with 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.

Always take Valsartan with a glass of water (200 – 250 ml of water).

You can take Valsartan with or without food.

*Patients with high blood pressure*

The usual dose is 80 mg valsartan once daily.

In some cases, your doctor may later decide to increase the dose to 160 mg or 320 mg valsartan daily or prescribe you further medication (e.g. a diuretic).

*Patients who have recently passed a heart attack*

Treatment with this drug usually starts 12 hours after heart attack. In this case, the initial dose is 20 mg, twice a day, which increases gradually for several weeks up to a maximum dose of 160 mg, twice a day.

In some cases, the doctor may prescribe you other medicines to treat heart attack. The final dose of your medication may depend on individual patient tolerance. Your doctor will decide the appropriate treatment for you.

*Patients with heart failure*

The usual initial dose is 40 mg, twice a day, which increases gradually over several weeks, up to a maximum dose of 160 mg, twice a day. Your doctor will decide the appropriate treatment for you.

In some cases, the doctor may prescribe you other medicines to treat heart failure. The final dose of your medication may depend on individual patient tolerance.

*Children and adolescents (below 18 years of age)*

Use of Valsartan is not recommended in children and adolescents below 18 years of age.

*Elderly patients (over 65 years)*

You may also take Valsartan if you are 65 years of age or over.

**If you take more Valsartan than you should**

If you take more Valsartan than you should, or if the children take it accidentally, please contact your doctor, the hospital or any medical care site to seek advice on the risk and the appropriate measures. Signs of an overdose include severe dizziness, drowsiness and fainting.

**If you forget to take Valsartan**

If you forget to take one dose (or more than one dose) take the next dose in its usual time. Do not take a double dose (or higher) to make up for the forgotten dose(s).

**If you stop taking Valsartan**

Do not stop taking your medicine unless your doctor tells you to.

If you stop your treatment with Valsartan, the disease may get worse.

**4. POSSIBLE SIDE EFFECTS**

Like all medicines, Valsartan can cause side effects, although not everybody gets them.

The following frequency data are used in the evaluation of side effects:

Very common:	occur in more than 1 in 10 users
Common:	occur in less than 1 in 10, but more than 1 in 100 users
Uncommon:	occur in less than 1 in 100, but more than 1 in 1,000 users
Rare:	occur in less than 1 in 1,000, but more than 1 in 10,000 users
Very rare:	occur in less than 1 in 10,000 users
Not known:	frequency cannot be estimated from the available data

*Important side effects*

Some side effects may be serious. You must therefore stop taking Valsartan and consult your doctor immediately, if you experience any of the following symptoms:

- swelling of the face, tongue or throat;
- difficulties in swallowing;
- hives and difficulties in breathing.

*Other possible side effects**Common:*

- dizziness;
- low blood pressure with symptoms such as dizziness;
- decreased kidney function (signs of renal impairment).

*Uncommon:*

- allergic reaction with symptoms such as rash, itching, dizziness, swelling of face, lips, tongue or throat, difficulty breathing or swallowing (signs of angioedema);
- sudden loss of consciousness;
- severely decreased kidney function (signs of acute renal failure);
- muscle spasms, abnormal heart rhythm (signs of hyperkalaemia);
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs (signs of cardiac failure);
- headache;
- cough;
- abdominal pain;
- nausea;
- diarrhea;
- tiredness;
- weakness.

*Very rare:*

- intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting and diarrhoea.

*Not known:*

- rash, itching, together with some of the following signs or symptoms: fever, joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms (signs of serum sickness);
- 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, in severe cases, lead to anaemia);

- increase of level of potassium in the blood (which can, in severe cases, trigger muscle spasms, abnormal heart rhythm);
- increase of bilirubin in the blood (which can, in severe cases, trigger yellow skin and eyes);
- increase of level of blood urea nitrogen and increase of level of serum creatinine (which can indicate abnormal kidney function).

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 patients treated for high blood pressure than in patients treated for heart failure or after a recent heart attack.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. HOW TO STORE VALSARTAN**

Keep this medicine out of the sight and reach of children!

Do not use Valsartan after the expiry date which is stated on the package.

Store below 25°C!

Keep in the original package.

## **6. OTHER INFORMATION**

### **What Valsartan 80 mg film-coated tablets contain:**

The **active substance** is valsartan.

Each film-coated tablet contains 80 mg of valsartan.

The **excipients** are: microcrystalline cellulose silicified, crospovidone, magnesium stearate, colloidal anhydrous silica, polyvinyl alcohol, titanium dioxide, macrogol, talc, red iron oxide, yellow iron oxide.

### **Contents of the pack:**

Box with 30 film-coated tablets.

**Marketing Authorisation Holder (MAH) and Manufacturer:**

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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**This leaflet was last revised in January 2025.**