

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

### **VALSAN**

Film-coated tablets – 160 mg

(Valsartan)

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

#### **What is in this leaflet:**

1. What Valsan is and what it is used for
2. What you need to know before you take Valsan
3. How to take Valsan
4. Possible side effects
5. How to store Valsan
6. Other information

#### **1. WHAT VALSAN IS AND WHAT IT IS USED FOR**

Valsan contains the active substance valsartan, which is an antagonist of angiotensin II receptors. Angiotensin II, which is produced by the body, narrows blood vessels. This causes increased blood pressure. Valsan prevents the narrowing of blood vessels by blocking the effect of angiotensin II. It relaxes blood vessels and lowers blood pressure.

Valsan 160 mg film-coated tablets are used for:

- treatment of patients with high blood pressure (hypertension);

high blood pressure increases the workload of the heart and arteries; if untreated, it can damage the blood vessels of the brain, heart and kidneys and can lead to stroke, heart failure or renal insufficiency; high blood pressure increases the risk of heart attacks; by lowering your blood pressure to a normal value, you decrease the risk of developing these disorders;

- treatment of patients who have recently experienced a heart attack (myocardial infarction) (12 hours to 10 days);
- treatment of adult patients with symptomatic heart failure, when treatment with other specific drugs (known as ACE-inhibitors, used in the treatment of heart failure) is not suitable. However, Valsan can be taken together with ACE-inhibitors, if other medications to treat heart failure can not be used. Symptoms of heart failure include shortness of breath and sweating of the feet due to fluid accumulation in these limbs. This is caused when the heart muscle can not pump the amount of blood needed to supply the entire body.

## **2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE VALSAN**

### **Do not take Valsan:**

- if you are sensitive to valsartan or to any of the excipients of Valsan;
- if you have severe hepatic impairment or if you suffer from hepatic diseases;
- if you are more than three months pregnant (it is also best to avoid treatment with Valsan in the first months of pregnancy);
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If any of these cases applies to you, do not take Valsan.

### **Take special care with Valsan**

#### Ask your doctor before you take Valsan:

- if you have kidney function disorder or if you are subject of dialysis;
- if you have liver function disorder;
- if you are aware that you have a narrowing or obstruction of the blood vessels of the kidneys;
- if you recently performed a kidney transplant (you have got a new kidney);
- if you suffer from hyperaldosteronism, a disorder in which the adrenal glands produce a much

greater amount of the hormone known as aldosterone; if this applies to your case, the use of Valsan is not recommended;

- if you suffer from severe vomiting or diarrhea, because it can lead to substantial loss of body fluids or salts from the organism;
- if you are being treated with diuretics (used to increase the excretion of fluids through the kidneys);
- if you are taking potassium sparing diuretics or potassium preparations, if using substitute salts containing potassium or if you are using other drugs (like heparin), which increase the amount of potassium in the blood; it may be necessary to check the amount of potassium in the blood at regular intervals;
- if you are taking any of the following medicines used to treat high blood pressure:
  - an ACE-inhibitor (e.g. 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) (e.g. spironolactone, eplerenone) or beta-blockers (e.g. 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 Valsan”;
- if you have problems with heart valves or muscle, or if you have other serious concerns of the heart;
- if you are being treated for heart failure or after a heart attack, because your kidney function may worsen during treatment;
- consult your doctor if you are (or might become) pregnant. Valsan is not recommended in early pregnancy and can cause serious damage to the fetus after the first trimester of pregnancy.

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

## **Taking other medicines**

Concomitant treatment with other medicines may affect or be affected by Valsan. However, please contact your doctor or pharmacist if you are taking or you have recently taken other medicines, including those obtained without prescription. It may be necessary to change the dose, or in some cases to stop taking one of the drugs. This goes for drugs that are taken with prescription and for those taken without prescription.

Special care is recommended if you are taking any of the following medications during treatment with Valsan:

- other drugs for lowering blood pressure, especially diuretics, since the latter can further reduce blood pressure;
- drugs that increase the amount of potassium in the blood, such as potassium preparations, substitutes of salts that contain potassium or potassium sparing drugs such as some types of diuretics or some other drugs that increase the amount of potassium in the blood (like heparin);
- some types of analgesics called anti-inflammatory drugs (or nonsteroidal anti-inflammatory drugs); these drugs can make Valsan to be less effective in lowering blood pressure; if your kidney function is impaired, the concomitant use of these drugs with Valsan can cause deterioration of kidney function;
- lithium-containing drugs (drugs used to treat some types of psychiatric illnesses); do not use Valsan and lithium at the same time, unless you are under a strict monitoring by your doctor; in this case, the doctor should take special precautions (for example, blood tests);
- if you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Valsan” and “Take special care with Valsan”);
- if you are being treated after a cardiac arrest, it is not recommended the combination with an ACE - inhibitor (it is used to treat heart attack);
- if you are being treated for heart failure and at the same time being treated with ACE inhibitors together with certain other medicines which are known as mineralocorticoid receptors antagonists (MRA) (e.g. spironolactone, eplerenone) or beta-blockers (e.g. metoprolol), the triple combination is not recommended with Valsan.

**Children and adolescents (under 18 years)**

Valsan use is not recommended in children and adolescents under 18 years old.

**Elderly patients (over 65 years)**

You can also get Valsan if you are 65 years old or more.

**Pregnancy and breastfeeding**

You should consult with your doctor if you are (or might become) pregnant. Your doctor will advise you to stop the treatment with Valsan before you become pregnant or as soon as you become aware that you are pregnant and will advise you to get another drug instead of Valsan. Valsan is not recommended in the first months of pregnancy, and should not be taken after the first trimester, because it can cause serious damage to the fetus.

Consult your doctor if you are breastfeeding or will start breastfeeding. Valsan is not recommended for mothers who are breastfeeding their baby and your doctor may replace it with another drug, especially if your baby is newborn, or was born pre-term (less than 9 months). Consult your doctor or pharmacist before taking any drug.

**Driving and using machines**

Like many other medicines used to treat high blood pressure, Valsan in rare cases can cause dizziness and can affect the ability to concentrate. Before driving, using machinery or performing other activities that require concentration, make sure to know how Valsan affects you.

**3. HOW TO TAKE VALSAN**

Always take Valsan exactly as your doctor has advised you. Contact 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 more important to keep appointments with the doctor even if they are feeling well.

*Taking Valsan with food and drink*

Valsan can be taken with or without meals.

**General recommendations for the dosage:**

Valsan is available in the dose of 160 mg.

*Patients with high blood pressure*

The usual dose is 80 mg valsartan once daily. In some cases, your doctor may decide to increase the dose to 160 mg or 320 mg valsartan daily or prescribe you another drug (e.g. a diuretic).

*Patients who have recently undergone a heart attack*

Treatment generally begins 12 hours after the heart attack. In this case, the dose is 20 mg twice daily, and is increased gradually over several weeks, up to a maximum of 160 mg, twice daily. In some cases, your doctor may prescribe you other drugs to treat the heart attack. The final dose of your medication depends on your individual tolerance. Your doctor will decide the adequate treatment for you.

*Patients with heart failure*

The usual starting dose is 40 mg twice daily, which is gradually increased over several weeks, up to a maximum of 160 mg twice daily. Your doctor will decide which treatment is suitable for you.

In some cases, your doctor may prescribe you further medication to treat heart failure. The final dose of your medication depends on your individual tolerance.

Always take Valsan film - coated tablets with a glass of water.

You can take Valsan with or without food.

**If you have taken more Valsan**

If you have taken by mistake more than the amount of Valsan you should take, or if the children have taken this drug incorrectly, please contact your doctor, hospital or call the emergency to get

an opinion on the risk and advice for actions to be taken. Signs of an overdose include severe dizziness, drowsiness and fainting.

**If you forget to take Valsan**

If you forget a dose (or more doses), take the following dose when it is time to take the usual dose.

Do not take a double dose (or higher) to supplement the forgotten dose (doses).

**If you stop treatment with Valsan**

Do not stop the treatment with the tablets without the advice of your doctor. If you stop your treatment with Valsan, your disease can get worse.

**4. POSSIBLE SIDE EFFECTS**

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

The frequency of possible side effects appears in the table below:

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

**Important side effects:**

Some side effects can be severe. In case the following symptoms appear, you should stop your treatment with Valsan and should immediately consult your doctor.

The symptoms are:

- swelling of the face, tongue or throat,
- difficulties in swallowing,
- hives (nettle rash),
- difficulties in breathing.

### **Other possible side effects:**

#### *Common:*

- dizziness, postural 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 or lips or tongue or throat, difficulty breathing or swallowing (signs of angioedema);
- sudden loss of consciousness;
- spinning sensation;
- 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);

- purplished-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);
- elevation of liver function values (which can indicate liver damage) including an 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 with 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 VALSAN**

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

Do not use this medicine after the expiry date which is stated on the carton.

Store under 30°C!

Keep in the original package!

## **6. OTHER INFORMATION**

### **What Valsan 160 mg film-coated tablets contain:**

**The active substance** is Valsartan. Each film-coated tablet contains 160 mg of valsartan.

### **The excipients** are:

*tablet core:* microcrystalline cellulose, silicified, crospovidone, magnesium stearate, colloidal anhydrous silica;

*film-coat:* polyvinyl alcohol, macrogol, titanium dioxide, talc, red iron oxide, yellow iron oxide.

### **Content of the pack:**

Carton box with 30 film-coated tablets.

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

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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