Package leaflet: Information for the patient

Valsartan - 1 A Pharma® 40 mg film-coated tablets
Valsartan - 1 A Pharma® 80 mg film-coated tablets
Valsartan - 1 A Pharma® 160 mg film-coated tablets
Valsartan - 1 A Pharma® 320 mg film-coated tablets

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, please tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet
1. What Valsartan - 1 A Pharma is and what it is used for
2. What you need to know before you take Valsartan - 1 A Pharma
3. How to take Valsartan - 1 A Pharma
4. Possible side effects
5. How to store Valsartan - 1 A Pharma
6. Contents of the pack and other information

1 What Valsartan - 1 A Pharma is and what it is used for

Valsartan - 1 A Pharma belongs to a class of medicines which are known as angiotensin-II receptor antagonists and help to control high blood pressure. Angiotensin II is a substance in the body which constricts blood vessels and causes your blood pressure to rise. Valsartan - 1 A Pharma acts by blocking the effect of angiotensin II. This expands the blood vessels and lowers the blood pressure.

Valsartan - 1 A Pharma 40 mg film-coated tablets may be used for the treatment of three different conditions:

- for the treatment of high blood pressure in children and adolescents aged 6 to 18 years. High blood pressure increases the workload of the heart and arteries. If high blood pressure persists over a long period of time, it can damage the blood vessels of the brain, heart and kidneys. This can lead to stroke, or heart or kidney failure. High blood pressure increases the risk of a heart attack. Lowering your blood pressure to normal reduces the risk of developing these disorders.
- for the treatment of adult patients following a recent heart attack (myocardial infarction). Here, “recent” means between 12 hours and 10 days ago.
- for the treatment of symptomatic heart failure in adult patients. Valsartan - 1 A Pharma is used when another group of medicines called ACE inhibitors (which are also used to treat heart failure) cannot be used. Valsartan - 1 A Pharma can also be used in addition to ACE inhibitors when beta blockers (another medicine used to treat heart failure) cannot be used. Heart failure is associated with shortness of breath and swelling of the feet and legs due to fluid retention. Heart failure means that the heart muscle can no longer pump blood powerfully enough to supply the entire body with the required amount of blood.
Valsartan - 1 A Pharma 80 mg film-coated tablets may be used for the treatment of three different conditions:

- for the treatment of high blood pressure in adults and in children and adolescents aged 6 to 18 years. High blood pressure increases the workload of the heart and arteries. If high blood pressure persists over a long period of time, it can damage the blood vessels of the brain, heart and kidneys. This can lead to stroke, or heart or kidney failure. High blood pressure increases the risk of a heart attack. Lowering your blood pressure to normal reduces the risk of developing these disorders.

- for the treatment of adult patients following a recent heart attack (myocardial infarction). Here, “recent” means between 12 hours and 10 days ago.

- for the treatment of symptomatic heart failure in adult patients. Valsartan - 1 A Pharma is used when another group of medicines called ACE inhibitors (which are also used to treat heart failure) cannot be used. Valsartan - 1 A Pharma can also be used in addition to ACE inhibitors when beta blockers (another medicine used to treat heart failure) cannot be used. Heart failure is associated with shortness of breath and swelling of the feet and legs due to fluid retention. Heart failure means that the heart muscle can no longer pump blood with sufficient strength to supply the entire body with the required amount of blood.

Valsartan - 1 A Pharma 160 mg film-coated tablets can be used for the treatment of three different conditions:

- for the treatment of high blood pressure in adults and in children and adolescents aged 6 to 18 years. High blood pressure increases the workload of the heart and arteries. If high blood pressure persists over a long period of time, it can damage the blood vessels of the brain, heart and kidneys. This can lead to stroke, or heart or kidney failure. High blood pressure increases the risk of a heart attack. Lowering your blood pressure to normal reduces the risk of developing these disorders.

- for the treatment of adult patients following a recent heart attack (myocardial infarction). Here, “recent” means between 12 hours and 10 days ago.

- for the treatment of symptomatic heart failure in adult patients. Valsartan - 1 A Pharma is used when another group of medicines called ACE inhibitors (which are also used to treat heart failure) cannot be used. Valsartan - 1 A Pharma can also be used in addition to ACE inhibitors when beta blockers (another medicine used to treat heart failure) cannot be used. Heart failure is associated with shortness of breath and swelling of the feet and legs due to fluid retention. Heart failure means that the heart muscle can no longer pump blood with sufficient strength to supply the entire body with the required amount of blood.

Valsartan - 1 A Pharma® 320 mg film-coated tablets can be used

- for the treatment of high blood pressure in adults and in children and adolescents aged 6 to 18 years. High blood pressure increases the workload of the heart and arteries. If high blood pressure persists over a long period of time, it can damage the blood vessels of the brain, heart and kidneys. This can lead to stroke, or heart or kidney failure. High blood pressure increases the risk of a heart attack. Lowering your blood pressure to normal reduces the risk of developing these disorders.

2 What you need to know before you take Valsartan - 1 A Pharma

Do not take Valsartan - 1 A Pharma

- if you are allergic to valsartan or any of the other ingredients of this medicine listed in Section 6.
- if you have severe liver disease.
• if you **are more than three months pregnant.** (It is also recommended that Valsartan - 1 A Pharma not be used in the early stages of pregnancy, see Pregnancy and Breast-feeding.)
• if you suffer from diabetes mellitus or impairment of renal function and are being treated with aliskiren (a drug to lower blood pressure).

Do not take Valsartan - 1 A Pharma if any of these apply to you.

**Warnings and Precautions**

Please speak with your doctor before you take Valsartan - 1 A Pharma

• if you have liver disease
• if you have severe kidney disease or if you are undergoing dialysis
• if you suffer from a narrowing of the renal artery
• if you have recently received a kidney transplant (received a new kidney)
• if you are being treated for a heart attack or for symptomatic heart failure, your doctor should check your kidney function.
• if, besides symptomatic heart failure or a heart attack, you have another serious heart condition
• if, while taking other medications (including an ACE inhibitor), you have ever had a swelling of the tongue and face, caused by an allergic reaction called angioedema. If these symptoms occur while you are taking Valsartan - 1 A Pharma, stop taking Valsartan - 1 A Pharma immediately and do not take any more. See also section 4 "Possible side effects”.
• if you are taking medicines that increase the potassium in your blood. These include potassium supplements or potassium-containing salt substitutes, potassium-sparing medicines and heparin. It may become necessary to check the amount of potassium in your blood regularly.
• if you are under 18 years old and taking Valsartan -1 A Pharma along with other drugs that inhibit the renin-angiotensin-aldosterone system (medicines that lower blood pressure). Your doctor will check your kidney function and potassium levels in your blood at regular intervals.
• if you suffer from hyperaldosteronism, a disease in which your adrenal glands make too much of the hormone aldosterone. In this case, the use of Valsartan - 1 A Pharma is not recommended.
• if you have lost a lot of fluid due to diarrhoea or vomiting (meaning that you are dehydrated) or if you are taking high doses of drugs that promote the production of urine (diuretics).
• Tell your doctor if you suspect you may be pregnant (or are planning to become pregnant). Taking Valsartan - 1 A Pharma in the early phase of pregnancy is not recommended and Valsartan - 1 A Pharma can no longer be used after the third month of pregnancy, since the administration of Valsartan -1 A Pharma at this stage may cause serious birth defects in your unborn child (see Pregnancy and Breast-feeding).
• if you are taking any of the following medicines used to treat high blood pressure:
  – "ACE inhibitors” such as enalapril, lisinopril, etc.
  – Aliskiren.

If any of these apply to you, tell your doctor before taking Valsartan - 1 A Pharma.

**Taking Valsartan - 1 A Pharma together with other medicines**

Tell your doctor or pharmacist if you are taking/using any other medicines, have recently taken/used any other medicines or might take/use other medicines.

The success of treatment can be affected if Valsartan - 1 A Pharma is used with certain other medicines. In some cases, it may be necessary to change the dose, take other precautions or stop taking a medicine.

This applies to both prescription and non-prescription medicines, especially:
• Other medicines that lower blood pressure, especially medicines that promote urine production (diuretics), ACE inhibitors (such as enalapril, lisinopril, etc.) or aliskiren
• Medicines that increase the potassium in your blood. These include potassium supplements or potassium-containing salt substitutes, potassium-sparing medicines and heparin.
• Certain pain medicines, referred to as non-steroidal anti-inflammatory drugs (NSAIDs)
• Some antibiotics (rifamycin group), a drug that is used to protect against transplant rejection (cyclosporin), or an antiretroviral drug which is used in the treatment of HIV/AIDS (ritonavir). These medicines may increase the effect of Valsartan - 1 A Pharma.
• Lithium, a medicine used to treat psychiatric disorders.

Also:
• if you are being treated after a heart attack, combination with an ACE inhibitor (a medicine used to treat a heart attack) is not recommended.
• if you are being treated for symptomatic heart failure, a triple combination with ACE inhibitors and beta-blockers (medicines used to treat heart failure) is not recommended.

Taking Valsartan - 1 A Pharma with food and drink
You can take Valsartan - 1 A Pharma with or without food.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
• Tell your doctor if you think you may be pregnant (or are planning to become pregnant). Typically, your doctor will recommend that you stop taking Valsartan - 1 A Pharma before you become pregnant or as soon as you know you are pregnant, and will recommend another medicine for you. The use of Valsartan -1 A Pharma in early pregnancy is not recommended and Valsartan - 1 A Pharma must not be used after the third month of pregnancy, since taking Valsartan
  – 1 A Pharma at this stage can result in serious harm to your unborn child.

Breast-feeding
• Tell your doctor if you are breast-feeding or are planning to breast-feed. Valsartan -1 A Pharma is not recommended for use in women who are breast-feeding, and your doctor may choose another treatment for you if you want to breast-feed, especially if your baby is a newborn, or was born prematurely.

Continued on back >>

Driving and using machines
Before you drive a vehicle, use tools or machines, or perform other activities that require concentration, make sure you know how you respond to the effects of Valsartan - 1 A Pharma. Like many other medicines used to treat high blood pressure, Valsartan - 1 A Pharma can, in rare cases, cause dizziness and affect the ability to concentrate.

How to take Valsartan - 1 A Pharma
Always take this medicine exactly as your doctor has told you, in order to achieve the best treatment outcome and to reduce the risk of side effects. Check with your doctor or pharmacist if you are not sure. People with high blood pressure often do not notice any signs of the problem. Many may feel completely healthy. This makes it even more important to keep your appointments with your doctor even if you feel well.
**Adult patients with hypertension:** The recommended dose is 80 mg per day. In some cases, your doctor may prescribe a higher dose (for example, 160 mg or 320 mg) or an additional medicine for you to take (for example, a diuretic).

**Children and adolescents (aged 6-18 years) with high blood pressure:** In patients who weigh less than 35 kg, the recommended dose is 40 mg valsartan once daily. In patients who weigh 35 kg or more, the usual starting dose is 80 mg valsartan once daily. In some cases, your doctor may prescribe higher doses (the dose may be increased to 160 mg and up to a maximum of 320 mg).

**Adult patients after a recent heart attack:** After a heart attack, treatment is generally already started after 12 hours, usually at a low dose of 20 mg 2 times daily. A dose of 20 mg can be obtained by splitting the 40 mg tablet. Your doctor will gradually increase the dose over several weeks up to a maximum of 160 mg 2 times daily. The final dose depends on the dose you can personally tolerate. Valsartan - 1 A Pharma can be given with other medicines for the treatment of heart attack, and your doctor will decide which treatment is suitable for you.

**Adult patients with heart failure:** Treatment generally begins at a dose of 40 mg 2 times daily. Your doctor will gradually increase the dose over several weeks up to a maximum of 160 mg 2 times daily. The final dose depends on the dose you can personally tolerate. Valsartan - 1 A Pharma can be given together with other medicines to treat heart failure, and your doctor will decide which treatment is right for you.

You can take Valsartan - 1 A Pharma with or without food. Swallow the tablets with a glass of water.
Take Valsartan - 1 A Pharma every day around the same time.

**If you take more Valsartan - 1 A Pharma than you should**
If you experience severe dizziness and/or you feel faint, tell your doctor immediately and lie down. If you accidentally take too many tablets, immediately contact your doctor or hospital.

**If you forget to take Valsartan - 1 A Pharma**
If you miss a dose, take it as soon as you remember. However, if it is almost time to take the next dose, skip the missed dose.
Do not take a double dose to make up for a forgotten dose.

**If you stop taking Valsartan - 1 A Pharma**
Stopping treatment with Valsartan -1 A Pharma can make your illness worse. Do not stop treatment unless your doctor tells you that you should stop the treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### Possible side effects

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

**Some symptoms need immediate medical attention:**
You may experience symptoms of angioedema (a specific allergic reaction), such as
- Swelling of face, lips, tongue, or throat
- Difficulty breathing or swallowing
- Hives and itching.

**If you notice one or more of these symptoms, see a doctor immediately (see also section 2 "Warnings and Precautions").**

**Possible side effects include:**
**Common:** 1 to 10 in 100 patients are affected
• Dizziness
• Low blood pressure with or without symptoms, such as dizziness and fainting when standing
• Reduced kidney function (signs of renal impairment)

**Uncommon:** 1 to 10 patients in 1,000 are affected
• Angiooedema (see the section “Some symptoms require immediate medical attention”)
• Sudden loss of consciousness (syncope)
• Spinning sensation (vertigo)
• Severely decreased kidney function (signs of acute renal failure)
• Muscle cramps, cardiac arrhythmia (signs of hyperkalaemia)
• Shortness of breath, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure)
• Headache
• Cough
• Abdominal pain
• Nausea
• Diarrhoea
• Fatigue
• Weakness

**Not known** from the available data:
• Allergic reactions with rash, itching or hives, symptoms such as fever, swollen joints and joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms (signs of serum sickness) may occur.
• Purple dot-like skin lesions, fever, itching (signs of inflammation of the blood vessels, referred to as vasculitis)
• Unusual bleeding or bruising (signs of thrombocytopenia)
• Muscle pain (myalgia)
• Fever, sore throat or mouth ulcers due to infections (symptoms of low numbers of white blood cells, also known as neutropenia)
• Decreased haemoglobin levels and a decreased percentage of red blood cells in the blood (which in severe cases can lead to anaemia)
• Increased levels of potassium in the blood (which can cause muscle spasms and arrhythmias in severe cases)
• Elevated liver function tests (which may indicate liver damage) including an increase in bilirubin in the blood (which can, in severe cases, cause yellowing of the skin and the lining of the inside of the eyelid and the white of the eyes)
• Increase in urea nitrogen in the blood and increased serum creatinine (which may indicate impaired renal function)
• Decreased levels of sodium in the blood (which can cause tiredness, confusion, muscle twitching and/or cramping in severe cases)

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

The side effects in children and adolescents are similar to the side effects observed in adults.

**Reporting of side effects**

*If you get any side effects, please tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.* You can also report side effects directly to the

Federal Institute for Drugs and Medical Devices
Department of Pharmacovigilance
By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Valsartan - 1 A Pharma

Store below 30 °C. Store in the original packaging to protect the contents from moisture.

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

Do not use this medicine after the expiry date stated on the carton. The expiry date refers to the last day of that month.

Do not take Valsartan - 1 A Pharma if the packaging is damaged, or if you suspect that the product is counterfeit.

Do not dispose of medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Valsartan - 1 A Pharma contains

The active substance is valsartan.

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

The other ingredients are: Microcrystalline cellulose, crospovidone (type A), colloidal silica, magnesium stearate (Ph. Eur.)

The film coating contains: Hypromellose, titanium dioxide (E 171), macrogol 8000, iron (III) oxide (E 172, red), iron (III) hydroxide oxide x H₂O (E 172, yellow), while Valsartan - 1 A Pharma 40 mg, 160 mg and 320 mg also contain iron (II, III) oxide (E 172, black)

What Valsartan - 1 A Pharma looks like and the contents of the pack

Valsartan - 1 A Pharma 40 mg film-coated tablets are yellow, ovaloid, slightly convex film-coated tablets with bevelled edges and scored on one side. On one side of the breaking groove a "D" is embossed and on the other side of the breaking groove an "O" is embossed, with "NVR" embossed on the reverse side of the film-coated tablet. The tablet can be divided into equal halves.

Valsartan - 1 A Pharma 80 mg tablets are round, pale-red, slightly convex film-coated tablets with bevelled edges and scored on one side. On one side of the breaking groove "D" is embossed and "V" is embossed on the other side of the breaking groove, and "NVR" is embossed on the reverse side of the film-coated tablet. The scoring line is only intended for splitting the tablet for easier swallowing, and not for splitting into equal doses.

Valsartan - 1 A Pharma 160 mg tablets are oval, grey-orange, slightly convex film-coated tablets with a breaking groove on one side. On one side of the tablet, on both sides of the breaking groove, "DX" is embossed, and on the reverse side of the film-coated tablet "NVR" is embossed. The score line is only intended for splitting the tablet for easier swallowing, and not for splitting into equal doses.

Valsartan - 1 A Pharma 320 mg film-coated tablets are dark grey-violet, oval, slightly convex film-coated tablets with bevelled edges and a breaking groove on one side. On one side of the tablet, on both sides of the breaking groove, "DC" is embossed, and on the reverse side of the film-coated tablet "NVR" is embossed. The score line is only intended for splitting the tablet for easier swallowing, and not for splitting into equal doses.
Valsartan - 1 A Pharma is provided in blister packs containing 28, 56 or 98 film-coated tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
1 A Pharma GmbH
Keltenring 1 + 3
82041 Oberhaching
Phone: 089/6138825-0

Manufacturer
Lek Pharmaceuticals d.d.
Verovskova 57
1526 Ljubljana
Slovenia

This medicine is approved in the member countries of the European Economic Area (EEA) under the following names:
Sweden VIVENDAL 40 mg Filmdragerad tablett
Austria Valsartan - 1A Pharma 40 mg - Filmtabletten
Germany Valsartan - 1 A Pharma 40 mg Filmtabletten
Poland Valsartan - 1 A Pharma
Sweden VIVENDAL 80 mg Filmdragerad tablett
Austria Valsartan - 1A Pharma 80 mg - Filmtabletten
Deutschland Valsartan - 1 A Pharma 80 mg Filmtabletten
Poland Valsartan - 1 A Pharma
Sweden VIVENDAL 160 mg Filmdragerad tablett
Austria Valsartan - 1 A Pharma 160 mg - Filmtabletten
Germany Valsartan - 1 A Pharma 160 mg Filmtabletten
Poland Valsartan - 1 A Pharma
Sweden VIVENDAL 320 mg Filmdragerad tablett
Austria Valsartan - 1A Pharma 320 mg - Filmtabletten
Germany Valsartan - 1 A Pharma 320 mg Filmtabletten
Poland Valsartan - 1 A Pharma

This leaflet was last revised in June 2013.

Please keep the medicine of the sight and reach of children!
1 A Pharma GmbH wishes you a speedy recovery!
46112482