

## Package leaflet: Information for the user

**[Valsartan 40 mg Film-coated Tablets and associated names]**  
**[Valsartan 80 mg Film-coated Tablets and associated names]**  
**[Valsartan 160 mg Film-coated Tablets and associated names]**  
**[Valsartan 320 mg Film-coated Tablets and associated names]**

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. See section 4.

### What is in this leaflet:

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

### 1. What [Valsartan] is and what it is used for

[Valsartan] belongs to a class of medicines known as angiotensin II receptor antagonist, which help to control high blood pressure. Angiotensin II is a substance in the body that causes vessels to tighten, thus 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.

[Valsartan] 40 mg film-coated tablets **can be used for three different conditions:**

- **to treat high blood pressure in children and adolescents 6 to less than 18 years of age.** 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. Lowering your blood pressure to normal reduces the risk of developing these disorders.
- **to treat adult patients after a recent heart attack** (myocardial infarction). “Recent” here means between 12 hours and 10 days.
- **to treat symptomatic heart failure in adult patients.** [Valsartan] is used when a group of medicines called Angiotensin Converting Enzyme (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.

[Valsartan] 80 mg film-coated tablets **can be used for three different conditions:**

- **to treat high blood pressure in adults and in children and adolescents 6 to less than 18 years of age.** 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. Lowering your blood pressure to normal reduces the risk of developing these disorders.

- **to treat adult patients after a recent heart attack** (myocardial infarction). “Recent” here means between 12 hours and 10 days.
- **to treat symptomatic heart failure in adult patients.** [Valsartan] is used when a group of medicines called Angiotensin Converting Enzyme (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.

[Valsartan] 160 mg film-coated tablets **can be used for three different conditions:**

- **to treat high blood pressure in adults and in children and adolescents 6 to less than 18 years of age.** 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. Lowering your blood pressure to normal reduces the risk of developing these disorders.
- **to treat adult patients after a recent heart attack** (myocardial infarction). “Recent” here means between 12 hours and 10 days.
- **to treat symptomatic heart failure in adult patients.** [Valsartan] is used when a group of medicines called Angiotensin Converting Enzyme (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.

[Valsartan] 320 mg film-coated tablets **can be used**

- **to treat high blood pressure in adults and in children and adolescents 6 to less than 18 years of age.** 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. Lowering your blood pressure to normal reduces the risk of developing these disorders.

## 2. What you need to know before you take [Valsartan]

### Do not take [Valsartan]

- 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 3 months pregnant**, (it is also better to avoid [Valsartan] in early pregnancy - see section 2: Pregnancy, breast-feeding and fertility).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing **aliskiren**

**If any of these apply to you, tell your doctor and do not take [Valsartan].**

### Warnings and precautions

Talk to your doctor or pharmacist before taking [Valsartan].

- 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 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 [Valsartan] is not recommended.
- if you have lost a lot of fluid (dehydration) caused by diarrhoea, vomiting, or high doses of water tablets (diuretics).
- if you have ever experienced swelling of the tongue and face caused by an allergic reaction called angioedema when taking another drug (including ACE inhibitors), tell your doctor. If these symptoms occur when you are taking [Valsartan], stop taking [Valsartan] immediately and never take it again (see section 4, "Possible side effects").
- you must tell your doctor if you think you are (or might become) pregnant. [Valsartan] is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see section 2: Pregnancy, breast-feeding and fertility).
- 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 any of these apply to you, tell your doctor before you take [Valsartan].**

#### **Other medicines and [Valsartan]**

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

The effect of the treatment can be influenced if [Valsartan] 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**).
- some antibiotics (rifamycin group), a drug used to protect against transplant rejection (ciclosporin) or an antiretroviral drug used to treat HIV/AIDS infection (ritonavir). These drugs may increase the effect of [Valsartan].
- **lithium**, a medicine used to treat some types of psychiatric illness.

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 [Valsartan]' 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 betablockers (for example metoprolol).

#### **[40mg, 80 mg and 160 mg]**

##### **In addition:**

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

### **[Valsartan] with food and drink**

You can take [Valsartan] with or without food.

### **Pregnancy, breast-feeding and fertility**

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

- **You must tell your doctor if you think you are (or might become) pregnant.** Your doctor will normally advise you 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 early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if it is used after the third month of pregnancy.
- **Tell your doctor if you are breast-feeding or about to start breast-feeding.** [Valsartan] is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

### **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 [Valsartan] affects you. Like many other medicines used to treat high blood pressure, [Valsartan] may cause dizziness and affect the ability to concentrate.

### **[Valsartan] contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

### **[Valsartan][320 mg] contains sunset yellow FCF (E110)**

This medicinal product contains sunset yellow FCF (E110) and may cause allergic reactions.

## **3. How to take [Valsartan]**

Always take this medicine 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.

[80 mg, 160 mg and 320 mg]

**Adults with high blood pressure:** The recommended dose is 80 mg daily. In some cases your doctor may prescribe higher doses (e.g. 160 mg or 320 mg). He may also combine [Valsartan] with an additional medicine (e.g. a diuretic).

[40 mg, 80 mg, 160 mg and 320 mg]

**Children and adolescents (6 to less than 18 years of age) with high blood pressure:** In patients who weigh less than 35 kg the recommended starting dose is 40 mg of valsartan once daily. In patients who weigh 35 kg or more the recommended starting dose is 80 mg of valsartan 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).

[40mg, 80 mg and 160 mg]

**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.

[Valsartan] 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.

[Valsartan] can be given together with other treatment for heart failure, and your doctor will decide which treatment is suitable for you.

You can take [Valsartan] with or without food. Swallow [Valsartan] with a glass of water.

Take [Valsartan] at about the same time each day.

The tablet can be divided into equal doses.

#### **If you take more [Valsartan] than you should**

If you experience severe dizziness and/or fainting, contact your doctor immediately and lie down. If you have accidentally taken too many tablets, contact your doctor, pharmacist, or hospital.

#### **If you forget to take [Valsartan]**

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.

#### **If you stop taking [Valsartan]**

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

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

## **4. Possible side effects**

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

#### **Some side effects can be serious and need immediate medical attention:**

You may experience symptoms of angioedema (a specific allergic reaction), an uncommon side effect, such as

- swollen face, lips, tongue or throat
- difficulty in breathing or swallowing
- hives, itching

**If you get any of these, stop taking [Valsartan] and contact your doctor straight away (see also section 2 “Warnings and precautions”).**

#### **Other side effects include:**

*Common (may affect up to 1 in 10 people):*

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

*Uncommon (may affect up to 1 in 100 people):*

- sudden loss of consciousness (syncope)
- spinning sensation (vertigo)
- 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
- diarrhoea
- tiredness
- weakness
- increase creatinine in the blood (which can indicate abnormal kidney function)

*Not known (frequency cannot be estimated from the available data):*

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

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

Side effects in children and adolescents are similar to those seen in adults.

**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.**

### **Reporting of side effects**

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

You can also report side effects directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store [Valsartan]**

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 and blister after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from moisture.

Do not use [Valsartan] if you notice that the pack is damaged or shows signs of tampering.

Do not throw away any medicines via wastewater or household waste. 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] contains

- The active substance is valsartan.
  - 40 mg: Each film-coated tablet contains 40 mg of valsartan
  - 80 mg: Each film-coated tablet contains 80 mg of valsartan
  - 160 mg: Each film-coated tablet contains 160 mg of valsartan
  - 320 mg: Each film-coated tablet contains 320 mg of valsartan
- The other ingredients are colloidal anhydrous silica, sodium starch glycolate (type A), crospovidone, microcrystalline cellulose, maize starch, magnesium stearate, hypromellose, macrogol, titanium dioxide (E171), talc, 40 and 160 mg: yellow iron oxide (E172), 80 and 160 mg: red iron oxide (E172), 320 mg: red iron oxide (E172), indigotine (E132), sunset yellow FCF (E110).

### What [Valsartan] looks like and contents of the pack

[Valsartan 40 mg Film-coated Tablets] are yellow, oval-shaped, film-coated tablets, scored on one side and debossed with “V” on one side of the score line and “40” on the other side of the score line.]

[Valsartan 80 mg Film-coated Tablets] are pink, oval-shaped, film-coated tablets, scored on one side and debossed with “V” on one side of the score line and “80” on the other side of the score line.]

[Valsartan 160 mg Film-coated Tablets] are yellow, oval-shaped, film-coated tablets, scored on one side and debossed with “V” on one side of the score line and “160” on the other side of the score line.]

[Valsartan 320 mg Film-coated Tablets] are purple, oval-shaped, film-coated tablets, scored on one side and debossed with “V” on one side of the score line and “320” on the other side of the score line.]

[Valsartan 40 mg Film-coated Tablets] are available in pack size of 1, 7, 14, 15, 28, 30, 56, 60, 84, 90, 98, 100 and 280 film-coated tablets. Hospital pack: 50, 56 (56 x 1), 98 (98 x 1) and 280 (280 x 1) film-coated tablets.]

[Valsartan 80 mg Film-coated Tablets] are available in pack size of 1, 14, 15, 28, 30, 56, 60, 84, 90, 98, 100 and 280 film-coated tablets. Hospital pack: 50 film-coated tablets. Calendar pack of 28 and 98 tablets.]

[Valsartan 160 mg Film-coated Tablets] are available in pack size of 1, 14, 15, 28, 30, 56, 60, 84, 90, 98, 100 and 280 film-coated tablets. Hospital pack: 50 film-coated tablets. Calendar pack of 28 and 98 tablets.]

[Valsartan 320 mg Film-coated Tablets] are available in pack size of 1, 7, 10, 14, 15, 20, 28, 30, 50, 56, 84, 90, 98, 100, 280 film-coated tablets. Hospital pack: 50, 56 x 1, 98 x 1 and 280 x 1 film-coated tablets.]

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

<To be completed nationally>

{Name and address }

<{tel}>

<{fax}>

<{e-mail}>

**This medicinal product is authorised in the member states of the EEA under the following names:**

Name of Member State	Name of the medicinal product
Denmark	Valsartan Teva 40 mg, 80 mg, 160 mg, 320 mg filmovertrukne tabletter
Spain	Valsartan Teva-ratiopharm 40 mg, 80 mg, 160 mg, 320 mg comprimidos recubiertos con película EFG
France	Valsartan TEVA 40 mg, 80 mg, 160 mg comprimé pelliculé sécable
Hungary	Valsartan-Teva 80 mg, 160 mg, 320 mg filmtabletta
Ireland	Valsartan Teva 40 mg, 80 mg, 160 mg Film-coated Tablets
Netherlands	Valsartan 40 mg, 80 mg, 160 mg, 320 mg PCH, filmomhulde tabletten
Poland	Bespres, 80 mg, 160 mg, tabletki powlekane
Portugal	Valsartan Teva 40 mg, 80 mg, 160 mg, 320 mg Comprimidos revestidos por película

**This leaflet was last revised in {MM/YYYY}.**

[To be completed nationally]