

Package leaflet: Information for the user

Valtan 160 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, 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 Valtan is and what it is used for
2. What you need to know before you take Valtan
3. How to take Valtan
4. Possible side effects
5. How to store Valtan
6. Contents of the pack and other information

1. What Valtan is and what it is used for

Valtan 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. Valtan works by blocking the effect of angiotensin II. As a result, blood vessels relax and blood pressure is lowered.

Valtan 160 mg film-coated tablets **can be used for three different conditions:**

- **to treat high blood pressure in adult and in children and adolescents 6 to 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.** Valtan 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.

2. What you need to know before you take Valtan

Do not take Valtan

- 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 have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- if you are **more than 3 months pregnant** (it is also better to avoid Valtan in early pregnancy – see pregnancy section)

If any of these apply to you, do not take Valtan.

Warnings and precautions

Talk to your doctor or pharmacist before taking Valtan

- 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 are treated after a heart attack or for heart failure, your doctor may check your kidney function
- 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 are below 18 years of age and you take Valtan in combination with other medicines that inhibit the renin angiotensin aldosterone system (medicines that lower blood pressure), your doctor may check your kidney function and 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 Valtan 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 experienced swelling, particularly of the face and throat, while taking other medicines (including angiotensin converting enzyme inhibitors). If you get these symptoms, when you are taking this medicine, stop taking this medicine and contact your doctor straight away. You should never take this medicine or any other valsartan containing medicines again
- you must tell your doctor if you think you are (or might become) pregnant. Valtan 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 pregnancy section)
- 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 Valtan”

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

Other medicines and Valtan

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 Valtan is taken together with certain other medicines. Your doctor may need to change your dose and/or 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**)
- **lithium**, a medicine used to treat some types of psychiatric illness
- 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 Valtan.
- if you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Valtan” 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)

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

Valtan with food and drink

You can take Valtan 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.

- **You must tell your doctor if you think that you are (or might become) pregnant.** Your doctor will normally advise you to stop taking Valtan before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Valtan. Valtan 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.** Valtan 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 Valtan affects you. Like many other medicines used to treat high blood pressure, Valtan may cause dizziness and affect the ability to concentrate.

Valtan contains milk sugar (lactose) and sodium

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3. How to take Valtan

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.

Adult patients 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 Valtan with an additional medicine (e.g. a diuretic).

Children and adolescents (6 to 18 years of age) with high blood pressure

In patients who weigh less than 35 kg the recommended 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).

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.

Valtan 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.

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

Method of administration

You can take Valtan with or without food. The tablet can be divided into equal doses. Swallow Valtan with a glass of water.

Take Valtan at about the same time each day.

If you take more Valtan 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 Valtan

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 Valtan

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

If you have 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 symptoms need immediate medical attention:

You may experience symptoms of angiooedema (a specific allergic reaction), such as

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

If you get any of these, see a doctor immediately.

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)

- angiooedema (see section “Some symptoms need immediate medical attention”)
- 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 (fatigue)
- weakness (asthenia)

Very rare (may affect up to 1 in 10 000 people)

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

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 and increase of level of serum creatinine (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 with 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.

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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Valtan

- 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 pack. The expiry date refers to the last day of that month.
- Do not use this medicine if you notice that the pack is damaged or shows signs of tampering.
- Do not store Valtan above 30°C.
- 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 Valtan contains

The active substance is valsartan.

Each Valtan 160 mg film-coated tablet contains 160 mg valsartan.

The other ingredients in the tablet core are:

- Lactose monohydrate
- Cellulose, powdered
- Hypromellose
- Croscarmellose sodium
- Silica, anhydrous colloidal
- Magnesium stearate

The other ingredients in the film coating are:

- Hypromellose
- Macrogol 8000
- Titanium dioxide (E171)
- Talc
- Iron oxide yellow (E172)

What Valtan looks like and contents of the pack

Valtan 160 mg film-coated tablets are yellow, oblong and biconvex in shape. They have a score line on both sides. The tablet can be divided into equal doses.

Valtan 160 mg film-coated tablets are packaged in PVC/PVDC aluminium blister packs containing 10, 14, 28, 30, 50, 56, 90, 98 and 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

For any information about this medicine, please contact the Marketing Authorisation Holder.

Manufacturers

Centrafarm Services BV, Van de Reijtstraat 31-E, 4814 NE Breda, The Netherlands

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Eurogenerics N.V., Heizel Esplanade Heysel b 22, B-1020 Brussels, Belgium

LAMP S. Prospero S.p.A., Via della Pace, 25/A, I-41030 San Prospero (Modena), Italy

STADA Arzneimittel AG, Stadastr. 2-18, D-61118 Bad Vilbel, Germany

STADA Arzneimittel GmbH, Muthgasse 36/2, A-1190 Wien, Austria

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium: Valsartan EG 160 mg filmomhulde tabletten

Bulgaria: Valsavil 160 mg филмирани таблетки

Denmark: Valsavil 160 mg, filmovertrukne tabletter

Finland: Valsarstad 160 mg tabletti, kalvopäällysteinen

Germany: Valsartan STADA 160 mg Filmtabletten
Ireland: Valtan 160 mg film-coated tablets
Italy: Valsartan EG 160 mg compresse rivestite con film
Luxembourg: Valsartan EG 160 mg comprimés pelliculés
Portugal: Valsartan Ciclum
Spain: Valsartán STADA 160 mg comprimidos recubiertos con película EFG
Sweden: Valsartore 160 mg filmdragerade tabletter
The Netherlands: Valsartan CF 160 mg, filmomhulde tabletten

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