Package leaflet: Information for the user

Valtan 320mg 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 320 mg film-coated tablets **can be used**
- **to treat high blood pressure in adults 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.

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 mellitus or impaired kidney function and you are treated with aliskiren (a medicine used to treat high blood pressure).
- 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, stop taking this medicine and contact your doctor straight away. You should never take any valsartan containing medicines (such as Valtan) again.
- if you are taking other medicines that are used to treat high blood pressure (see section "Other medicines and Valtan" below).
- 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).

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. 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**).
- **lithium**, a medicine used to treat some types of psychiatric illness.
- **aliskiren**, a medicine used to treat high blood pressure.

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 <u>(or might become)</u> 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)
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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).

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)

Not known (frequency cannot be estimated from the available data)
- 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,pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.
IRELAND: FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.

Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.imb.ie, e-mail: imbpharmacovigilance@imb.ie.

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 320 mg film-coated tablet contains 320 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)
- Iron oxide red (E172)
- Iron oxide black (E172)

What Valtan looks like and contents of the pack

Valtan 320 mg film-coated tablets are brown, oblong, and biconvex in shape. They have a break-line on one side, which can be used to divide the tablet into equal doses.

Valtan 320 mg film-coated tablets are packaged in PVC/PVDC aluminium blister packs containing 10, 14, 28, 30, 50, 56, 98, 100, 112, 126, 154, 168, 182 and 196 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, Nieuwe Donk 9, 4879 AC Etten Leur, 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
PharmaCoDane ApS, Marielundvej 46A, DK-2730 Herlev, Denmark
STADA Arzneimittel AG, Stadastr. 2-18, D-61118 Bad Vilbel, Germany
STADA Arzneimittel GmbH, Muthgasse 36/2, A-1190 Wien, Austria
STADA Production Ireland, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

Austria:	Valsavil 320 mg Filmtabletten
Belgium:	Valsartan EG 320 mg filmomhulde tabletten
Denmark:	Valsavil 320 mg, filmovertrukne tabletter
Finland:	Valsarstad 320 mg tabletti, kalvopäälllysteinen
Germany:	Valsartan STADA 320 mg Filmtabletten
Ireland:	Valtan 320 mg film-coated tablets
Italy:	Valsartan EG 320 mg compresse rivestite con film
Luxembourg:	Valsartan EG 320 mg comprimés pelliculés
Poland:	Valsavil
Portugal:	Valsartan STADA
Spain:	Valsartán STADA Genéricos 320 mg comprimidos recubiertos con película EFG
Sweden:	Valsartore 320 mg filmdragerade tabletter
The Netherlands:	Valsartan CF 320 mg, filmomhulde tabletten

This leaflet was last revised in August 2013.