

VALSAR-HT 80/12.5
(Valsartan and Hydrochlorothiazide Tablets USP 80/12.5 mg)

PATIENT INFORMATION LEAFLET

PATIENT SUMMARY OF INFORMATION ABOUT [VALSAR HT 80/12.5
(Valsaran and Hydrochlorothiazide USP Tablets USP 80/12.5 mg)]

Please read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them even if their symptoms 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.

In this leaflet:

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

1. WHAT VALSARTAN AND HYDROCHLOROTHIAZIDE TABLET USP 80/12.5 MG IS AND WHAT IT IS USED FOR

Valsartan and Hydrochlorothiazide is a contain two active substances called valsartan and hydrochlorothiazide.

Both of these substances help to control high blood pressure (hypertension).

Valsartan belongs to a class of medicines known as “angiotensin II receptor antagonists”, 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.

Hydrochlorothiazide belongs to a group of medicines called thiazide diuretics (also known as “water tablets”). Hydrochlorothiazide increases urine output, which also lowers blood pressure.

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The two active ingredients in Valsartan and Hydrochlorothiazide work together to lower blood pressure further than if either was given alone.

Valsartan and Hydrochlorothiazide is used to treat high blood pressure which is not adequately controlled by a single substance alone.

High blood pressure increases the workload of 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 AND HYDROCHLOROTHIAZIDE TABLET USP 80/12.5 MG

Do not take Valsartan and Hydrochlorothiazide

Do not take Valsartan and Hydrochlorothiazide:

- if you are allergic (hypersensitive) to valsartan, hydrochlorothiazide, sulphonamide derivatives
- if you are **more than 3 months pregnant** (it is also better to avoid Valsartan and Hydrochlorothiazide in early pregnancy – see pregnancy section).
- if you have **severe** liver disease, destruction of the small bile ducts within the liver (biliary cirrhosis) leading to the build up of bile in the liver (cholestasis).
- if you have **severe** kidney disease.
- if you are unable to produce urine (anuria).
- if you are treated with an artificial kidney.
- if the level of potassium or sodium in your blood is lower than normal, or if the level of calcium in your blood is higher than normal despite treatment.
- if you have gout.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Warnings and precautions

Talk to your doctor

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- if you are taking potassium-sparing medicines, potassium supplements, salt substitutes containing potassium or other medicines that increase the amount of potassium in your blood such as heparin. Your doctor may need to check the amount of potassium in your blood regularly.
- if you have low levels of potassium in your blood.
- if you have diarrhoea or severe vomiting.
- if you are taking high doses of water tablets (diuretics).
- if you have severe heart disease.
- if you are suffering from heart failure or have experienced a heart attack. Follow your doctor's instruction for the starting dose carefully. Your doctor may also check your kidney function.
- if you suffer from a narrowing of the kidney artery.
- if you have recently received a new kidney. if you suffer from hyperaldosteronism. 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 and Hydrochlorothiazide is not recommended.
- if you have liver or kidney disease.
- 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 and Hydrochlorothiazide, stop taking Valsartan and Hydrochlorothiazide immediately and never take it again. See also section 4, "Possible side effects".
- if you have fever, rash and joint pain, which may be signs of systemic lupus erythematosus (SLE, a so-called autoimmune disease).
- if you have diabetes, gout, high levels of cholesterol or triglycerides in your blood.
- if you have had allergic reactions with the use of other blood pressure-lowering agents of this class (angiotensin II receptor antagonists) or if you have allergy or asthma.

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- if you experience a decrease in vision or eye pain. These could be symptoms of an increase of pressure in your eye and can happen within hours to a week of taking Valsartan and Hydrochlorothiazide. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulphonamide allergy you can be at higher risk of developing this.
- if you are taking any of the following medicines used to treat high blood pressure:

- o an ACE inhibitors (for example enalapril, lisinopril, Ramipril), in particular if you have diabetes-related kidney problems.

- o aliskiren

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals. Other medicines and Valsartan and Hydrochlorothiazide Tablets

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

Valsartan and Hydrochlorothiazide may cause increased sensitivity of the skin to sun.

The use of Valsartan and Hydrochlorothiazide in children and adolescents (below the age of 18 years) is not recommended.

Other medicines and Valsartan and Hydrochlorothiazide

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

The effect of the treatment can be influenced if Valsartan and Hydrochlorothiazide 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 especially applies to the following medicines:

lithium, a medicine used to treat some types of psychiatric diseases.

- medicines or substances that may increase the amount of potassium in your blood. These include potassium supplements or salt substitutes containing potassium, potassium-sparing medicines and heparin.
- medicines that may reduce the amount of potassium in your blood, such as diuretics (water tablets), corticosteroids, laxatives, carbenoxolone, amphotericin or penicillin G.

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- some antibiotics (rifamycin group), a drug used to protect against transplant rejection (cyclosporin) or an antiretroviral drug used to treat HIV/AIDS infection (ritonavir). These drugs may increase the effect of Valsartan and Hydrochlorothiazide.
- medicines that may induce “torsades de pointes” (irregular heart beat), such as antiarrhythmics (medicines used to treat heart problems) and some antipsychotics.
- medicines that may reduce the amount of sodium in your blood, such as antidepressants, antipsychotics, antiepileptics.
- medicines for the treatment of gout, such as allopurinol, probenecid, sulfinpyrazone.
- therapeutic vitamin D and calcium supplements.
- medicines for the treatment of diabetes (oral agents such as metformin or insulins).
- other medicines to lower your blood pressure including methyldopa, ACE inhibitors (such as enalapril, lisinopril, etc.) or aliskiren (see also information under the headings “Do not take Valsartan and Hydrochlorothiazide” and “Warnings and precautions”). medicines to increase blood pressure, such as noradrenaline or adrenaline.
- digoxin or other digitalis glycosides (medicines used to treat heart problems).
- medicines that may increase blood sugar levels, such as diazoxide or beta blockers.
- cytotoxic medicines (used to treat cancer), such as methotrexate or cyclophosphamide.
- pain killers such as non-steroidal anti-inflammatory agents (NSAIDs), including selective cyclooxygenase-2 inhibitors (Cox-2 inhibitors) and acetylsalicylic acid > 3 g.
- muscle relaxing medicines, such as tubocurarine.
- anti-cholinergic medicines (medicines used to treat a variety of disorders such as gastrointestinal cramps, urinary bladder spasm, asthma, motion sickness, muscular spasms, Parkinson's disease and as an aid to anaesthesia).
- amantadine (medicine used to treat Parkinson’s disease and also used to treat or prevent certain illnesses caused by viruses).
- cholestyramine and colestipol (medicines used mainly to treat high levels of lipids in the blood).
- cyclosporin, a medicine used for organ transplant to avoid organ rejection.

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- alcohol, sleeping pills and anaesthetics (medicines with sleeping or painkilling effect used for example during surgery).
- iodine contrast media (agents used for imaging examinations).

Taking Valsartan and Hydrochlorothiazide with food, drink and alcohol

Avoid taking alcohol until you have talked to your doctor. Alcohol may make your blood pressure fall more and/or increase the risk of you becoming dizzy or feeling faint.

Pregnancy, breast-feeding and fertility

- **You must tell your doctor if you think that you are (or might become) pregnant**

Your doctor will normally advise you to stop taking Valsartan and Hydrochlorothiazide before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Valsartan and Hydrochlorothiazide. Valsartan and Hydrochlorothiazide 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 and Hydrochlorothiazide 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 new born, 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 and Hydrochlorothiazide affects you. Like many other medicines used to treat high blood pressure, Valsartan and Hydrochlorothiazide may occasionally cause dizziness and affect the ability to concentrate.

3. How to take Valsaran and Hydrochlorothiazide Tablets USP 80/12.5 mg

Always take this medicine exactly as your doctor has told you. This will help you to get the best results and lower the risk of side effects. Check with your doctor or pharmacist if you are not

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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 your doctor even if you are feeling well.

Your doctor will tell you exactly how many tablets of Valsartan and Hydrochlorothiazide to take. Depending on how you

respond to the treatment, your doctor may suggest a higher or lower dose.

The recommended dose of Valsartan and Hydrochlorothiazide is one tablet per day.

- Do not change the dose or stop taking the tablets without consulting your doctor.
- The medicine should be taken at the same time each day, usually in the morning.
- You can take Valsartan and Hydrochlorothiazide with or without food.
- Swallow the tablet with a glass of water.

If you take more Valsartan and Hydrochlorothiazide than you should

If you experience severe dizziness and/or fainting, lie down and contact your doctor immediately.

If you have accidentally taken too many tablets, contact your doctor, pharmacist or hospital.

If you forget to take Valsartan and Hydrochlorothiazide

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 and Hydrochlorothiazide

Stopping your treatment with Valsartan and Hydrochlorothiazide may cause your high blood pressure 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

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5. HOW TO STORE VALSARAN AND HYDROCHLOROTHIAZIDE TABLETS USP 80/12.5 mg.

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. The expiry date refers to the last day of that month.
- Do not store above 30°C. Store in the original package in order to protect from moisture.
- Do not use this medicine 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 Valsaran and Hydrochlorothiazide Tablets USP 80/12.5 mg contains

- The active substances are valsartan and hydrochlorothiazide. Each film-coated tablet of **Valsaran and Hydrochlorothiazide Tablets USP 80/12.5 mg** contains 80 mg Valsartan and 12.5 mg hydrochlorothiazide.
- The excipients such as Microcrystalline Cellulose (Vivapur 102) , Crospovidone (Kollidon CL), Magnesium Stearate, Colloidal Silicon Dioxide (Aerosil 200), Opadry orange and Purified water.

What VALSAR-HT 80/12.5 (Valsaran and Hydrochlorothiazide Tablets USP 80/12.5 mg) looks like and contents of the pack

light Orange colored, Oval, biconvex, film coated tablets debossed with H on one side and 'V6' on the other side

VALSAR-HT 80/12.5 (Valsaran and Hydrochlorothiazide Tablets USP 80/12.5 mg) is available in:

10's Blister.



Hetero

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Marketing Authorization Holder and Manufacturer

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