

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

1. What Valsartan Jubilant is and what it is used for

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

Valsartan Jubilant 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 Valsartan Jubilant

Do not take Valsartan Jubilant:

- if you are **allergic** to valsartan or any of the other ingredients of Valsartan Jubilant (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 Jubilant in early pregnancy - see pregnancy section).

- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine called aliskiren.

If any of these apply to you, do not take Valsartan Jubilant

Warnings and precautions

Talk to your doctor or pharmacist before taking Valsartan Jubilant:

- 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 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 Jubilant, stop taking Valsartan Jubilant immediately and never take it again. See also section 4, “Possible side effects”.
- 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 Valsartan Jubilant 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 Valsartan Jubilant is not recommended.
- if you have lost a lot of fluid (dehydration) caused by diarrhoea, vomiting, or high doses of water pills (diuretics).
- you must tell your doctor if you think you are (or might become) pregnant. Valsartan Jubilant 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, etc.), in particular if you have diabetes related kidney problems.
 - aliskiren

If any of these apply to you, tell your doctor before you take Valsartan Jubilant.

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

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

See also information under the heading “Do not take Valsartan Jubilant”.

Other medicines and Valsartan Jubilant

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 Jubilant 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), ACE inhibitors (such as enalapril, lisinopril, etc.) or aliskiren (See also information under the heading “Do not take Valsartan Jubilant” and “Warnings and precautions”).
- **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 Jubilant.
- **lithium**, a medicine used to treat some types of psychiatric illness.

Valsartan Jubilant with food and drink

You can take Valsartan Jubilant 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 Valsartan Jubilant before you become pregnant or as soon as you know you are pregnant, and will advise you to take another medicine instead of Valsartan Jubilant. Valsartan Jubilant 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 Jubilant 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 Jubilant affects you. Like many other medicines used to treat high blood pressure, Valsartan Jubilant may in rare cases cause dizziness and affect the ability to concentrate.

Valsartan Jubilant contains 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 Valsartan Jubilant

Always take Valsartan Jubilant exactly as your doctor has told you in order to get the best results and reduce the risk of side effects. You should 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 Valsartan Jubilant 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).

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

Take Valsartan Jubilant at about the same time each day.

If you take more Valsartan Jubilant 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 Jubilant

Do not take a double dose to make up for a forgotten dose.

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.

If you stop taking Valsartan Jubilant

Stopping your treatment with Valsartan Jubilant 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 product, 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 angioedema (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.

Other side effects include:

Common (may affect 1 to 10 users in 100):

- 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):

- angioedema (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
- weakness

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, in severe cases, lead to anaemia)
- increase of level of potassium in the blood (which can, in severe cases, trigger muscle spasms, abnormal heart rhythm)
- elevation of liver function values (which can indicate liver damage) including an increase of bilirubin in the blood (which can, in severe cases, trigger yellow skin and eyes)
- increase of level of blood urea nitrogen and increase of level of serum creatinine (which can indicate abnormal kidney function)
- low blood sodium (which can trigger tiredness, confusion, muscle twitching and/or convulsions in severe cases)
- blistering skin (sign of dermatitis bullous)

Very rare

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

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Valsartan Jubilant

- Keep this medicine out of the sight and reach of children.
- PVC/PE/PVDC blister: Store below 30 °C.
Al/Al blister: This medicine does not require any special storage conditions.
- Do not use this medicine after the expiry date which is stated on the pack after EXP. 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 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 to protect the environment.

6. Contents of the pack and other information**What Valsartan Jubilant 320 mg film-coated tablets contains**

- The active substance is valsartan.
Each film-coated tablet contains 320 mg valsartan.
- The other ingredients are:
Microcrystalline cellulose (E460), crospovidone (E1202), dental type silica, magnesium stearate (E470b), lactose anhydrous, hypromellose (E464), titanium dioxide (E171), macrogol, and iron oxide yellow (E172).

What Valsartan Jubilant 320 mg film-coated tablets looks like and contents of the pack

Valsartan Jubilant 320 mg film-coated tablets are yellow coloured, oval shaped, biconvex film-coated tablets of approximately 20,45 mm length and 9,65 mm width, debossed with 'C5' on one side and plain on the other side.

The tablets are available in blister packs of 28, 56 or 98 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

To be completed nationally

Manufacturer

PSI supply nv
Axxes Business Park
Guldensporenpark 22 – Block C
9820 Merelbeke
Belgium

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

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

Sweden:	Valsartan Jubilant 320 mg Filmdragerade Tabletter
Cyprus:	Valsartan Jubilant 320 mg Επικαλυμμένο με λεπτό υμένιο δισκίο
Denmark:	Valsartan Jubilant 320 mg Filmovertrukket tablet
The Netherlands:	Valsartan Jubilant 320 mg filmomhulde tabletten
United Kingdom:	Valsartan 320 mg film-coated tablets

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