

Valsartan Tablets USP 40mg/80mg/160mg/320mg Taj Pharma

(Valsartan)

Package leaflet: Information for the user

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 are and what they are used for
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1. What Valsartan are and what they are used for

Valsartan contain the active substance Valsartan TajPharma and 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 the blood vessels to tighten, causing your blood pressure to increase.

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

Valsartan TajPharma 40mg Tablets can be used for three different conditions:

- **to treat high blood pressure 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.** Valsartan TajPharma 40mg Tablets are 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 TajPharma 80mg and 160mg Tablets can be used for three different conditions:

- **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.

- **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 TajPharma 80mg and 160mg Tablets 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 Valsartan

Do not take Valsartan :

- if you are **allergic** to Valsartan TajPharma 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 pregnancy section).
- 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 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 being treated **after a heart attack or heart failure**, your doctor may check your kidney function.
- 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”
- 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 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 “

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 are taken together with certain other medicines. Your doctor may need to change your dose and/or 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.
- if you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Valsartan ” and “Warnings and precautions”).

In addition:

- 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).

- 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 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 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 are not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as they may cause serious harm to your baby if they are used after the third month of pregnancy.

Tell your doctor if you are breast-feeding or about to start breast-feeding.

Valsartan are not recommended if you are breast-feeding. 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 this medicine affects you. Like many other medicines used to treat high blood pressure,

Valsartan may in rare cases cause dizziness and affect the ability to concentrate.

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.

Take Valsartan at about the same time each day. Swallow the Tablets with a glass of water. You can take the Tablets with or without food.

Dosage:

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

In patients who weigh less than 35kg the recommended dose is 40mg of valsartan once daily.

In patients who weigh 35kg or more the recommended starting dose is 80mg of Valsartan TajPharma once daily.

In some cases your doctor may prescribe higher doses (the dose can be increased to 160mg and to a maximum of 320mg).

Adult patients with high blood pressure:

The recommended dose is 80mg capsule daily. In some cases your doctor may prescribe higher doses (e.g. 160mg or 320mg). You may also be prescribed an additional medicine to take e.g. "water tablets" (a diuretic).

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 20mg twice daily. You obtain the 20mg dose by dividing a 40mg tablet (obtained from a different source). Your doctor will increase this dose gradually over several weeks to a maximum of 160mg twice daily. The final

dose depends on what you as an individual patient can tolerate.

Valsartan Tablets can be given together with certain other treatments for heart attack, and your doctor will decide which treatment is suitable for you.

Adult patients with heart failure:

Treatment starts generally with 40mg capsule twice daily. Your doctor will increase the dose gradually over several weeks to a maximum of 160mg capsule twice daily. The final dose depends on what you as an individual patient can tolerate.

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

If you take more Valsartan Tablets 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 Tablets

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 Tablets

Stopping your treatment with Valsartan Tablets 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), such as

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

If you get any of these symptoms, stop taking Valsartan Tablets and contact your doctor straight away.

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 kidney 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 (feeling sick)
- diarrhoea
- tiredness
- weakness

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

- blistering skin (sign of dermatitis bullous)
- rash

- itching
- allergic reactions with rash, itching and hives together with some of the following signs or symptoms; 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 in level of haemoglobin and decrease of the percentage of red blood cells in the blood (which can, in severe cases, lead to anaemia)
- increase in 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 in 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.

5 How to store Valsartan

Store below 30°C.

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 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 protect the environment.

6. Contents of the pack and other information

What Valsartan Tablets contain

a) Each film coated tablet contains:
Valsartan USP 40mg
Excipients q.s.
Colour: Yellow Oxide Of Iron & Titanium
Dioxide USP

b) Each film coated tablet contains:
Valsartan USP 80mg
Excipients q.s.
Colour: Yellow Oxide Of Iron & Titanium
Dioxide USP

c) Each film coated tablet contains:
Valsartan USP 160mg
Excipients q.s.
Colour: Yellow Oxide Of Iron & Titanium
Dioxide USP

d) Each film coated tablet contains:
Valsartan USP 320mg
Excipients q.s.
Colour: Yellow Oxide Of Iron & Titanium
Dioxide USP

The other ingredients are:

Tablet core: Microcrystalline cellulose, Crospovidone, Povidone, Croscarmellose Sodium, Silica, colloidal anhydrous, Magnesium stearate.

Tablet coating: Hypromellose , Titanium dioxide, Macrogol, Iron oxide yellow.

What Valsartan Tablets look like and contents of the pack

Yellow, oval-shaped, biconvex, film-coated tablets.

PVC/PE/Aluminium blister pack.

Pack Size: 7, 14, 28, 30, 50, 100 and 500 tablets.

Not all packs may be marketed.

7. Manufactured In India By:

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