

Package leaflet: Information for the user

Valsartan Baldacci 40 mg film-coated tablets
Valsartan Baldacci 80 mg film-coated tablets
Valsartan Baldacci 160 mg film-coated tablets
Valsartan Baldacci 320 mg film-coated tablets

Valsartan

Read all this leaflet carefully before taking this medicine as it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you are not sure, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. You should not give it to others. The medicine can be harmful to them even if they show the same signs of illness.
- If you get any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist. See section 4.

What's in this leaflet:

1. What is Valsartan Baldacci and what it is used for
2. Or what you need to know before taking Valsartan Baldacci
3. How to Take Valsartan Baldacci
4. Possible side effects
5. How to store Valsartan Baldacci
6. Package contents and other information

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

Valsartan Baldacci contains the active substance: valsartan and belongs to a class of medicines known as angiotensin II receptor antagonists, which help control high blood pressure. Angiotensin II is a substance produced by the body that causes constriction of blood vessels, thus inducing an increase in blood pressure. Valsartan Baldacci works by blocking the effect of angiotensin II. Consequently, blood vessels dilate and blood pressure decreases.

Valsartan Baldacci 40 mg film-coated tablets can be used in three different situations:

- For the treatment of high blood pressure in children and adolescents from 6 to 18 years of age. High blood pressure increases the overload of the heart and arteries. If left untreated, it can cause damage to the blood vessels of the brain, heart and kidneys, which can lead to stroke, heart failure or kidney failure. High blood pressure increases the risk of heart attacks. Lowering blood pressure to normal values reduces the risk of developing these diseases.
 - For the treatment of adult patients after a recent heart attack (myocardial infarction). "Recent" here means between 12 hours and 10 days.
 - Valsartan Baldacci can be used for the treatment of symptomatic heart failure in adult patients. Valsartan Baldacci is used when a group of medicines called Angiotensin-converting enzyme (ACE) inhibitors (a medicine to treat heart failure) cannot be used, or it can be used in addition to ACE inhibitors, when other medicines to treat heart failure cannot be used.
- Symptoms of heart failure include shortness of breath and swelling of the feet and legs due to fluid buildup. It is caused when the heart muscle cannot pump blood hard enough to supply all the blood needed by the entire body.

Valsartan Baldacci 80 mg film-coated tablets can be used in three different situations:

- For the treatment of high blood pressure in adults and in children and adolescents from 6 to 18 years of age. High blood pressure increases the overload of the heart and arteries. If left untreated, it can cause damage to the blood vessels of the brain, heart and kidneys, which can lead to stroke, heart failure or kidney failure. High blood pressure increases the risk of heart attacks. Lowering blood pressure to normal values reduces the risk of developing these diseases.
- For the treatment of adult patients after a recent heart attack (myocardial infarction). "Recent" here means between 12 hours and 10 days.
- Valsartan Baldacci can be used for the treatment of symptomatic heart failure in adult patients. Valsartan Baldacci is used when a group of medicines called Angiotensin-Converting Enzyme (ACE) inhibitors (a medicine to treat heart failure) cannot be used, or it can be used in addition to ACE inhibitors when other medicines to treat heart failure cannot be used.

Symptoms of heart failure include shortness of breath and swelling of the feet and legs due to fluid buildup. It is caused when the heart muscle cannot pump blood hard enough to supply all the blood needed by the entire body.

Valsartan Baldacci 160 mg film-coated tablets can be used in three different situations:

- For the treatment of high blood pressure in adults and in children and adolescents from 6 to 18 years of age. High blood pressure increases the overload of the heart and arteries. If left untreated, it can cause damage to the blood vessels of the brain, heart and kidneys, which can lead to stroke, heart failure or kidney failure. High blood pressure increases the risk of heart attacks. Lowering blood pressure to normal values reduces the risk of developing these diseases.
- For the treatment of adult patients after a recent heart attack (myocardial infarction). "Recent" here means between 12 hours and 10 days.
- Valsartan Baldacci can be used for the treatment of symptomatic heart failure in adult patients. Valsartan Baldacci is used when a group of medicines called Angiotensin-Converting Enzyme (ACE) inhibitors (a medicine to treat heart failure) cannot be used, or it can be used in addition to ACE inhibitors when other medicines to treat heart failure cannot be used.

Symptoms of heart failure include shortness of breath and swelling of the feet and legs due to fluid buildup. It is caused when the heart muscle cannot pump blood hard enough to supply all the blood needed by the entire body.

Valsartan Baldacci 320 mg film-coated tablets may be used

- For the treatment of high blood pressure in adults and in children and adolescents from 6 to 18 years of age. High blood pressure increases the overload of the heart and arteries. If left untreated, it can cause damage to the blood vessels of the brain, heart and kidneys, which can lead to stroke, heart failure or kidney failure. High blood pressure increases the risk of heart attacks. Lowering blood pressure to normal values reduces the risk of developing these diseases.

2. What you need to know before taking Valsartan Baldacci

Don't take Valsartan Baldacci:

- If you are allergic to valsartan or any of the other ingredients of this medicine (mentioned in section 6).
- If you have severe liver disease.
- If you are more than 3 months pregnant (it is also best to avoid taking Valsartan Baldacci early in pregnancy - see section on pregnancy).

- If you have diabetes, or decreased kidney function, and are being treated with a medicine that contains aliskiren to lower blood pressure.

If any of the above apply to you, tell your doctor, and do not take Valsartan Baldacci

Warnings and precautions:

Talk to your doctor before using Valsartan Baldacci

- If you suffer from liver disease.
- If you have severe kidney disease or are on dialysis.
- If you suffer from narrowing of the renal artery.
- If you have recently had a kidney transplant (you have received a new kidney).

If you suffer from serious 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, while taking another medicine (including ACE inhibitors), tell your doctor. If you experience these symptoms while taking Valsartan Baldacci, stop taking Valsartan Baldacci immediately and do not take it again. See also section 4 "Side effects".

If you are taking medicines that increase the amount of potassium in your blood. These include potassium supplements or saline substitutes containing potassium, potassium-sparing medications, and heparin. You may need to check the level of potassium in your blood on a regular basis.

If you suffer from aldosteronism. It is a disease in which the adrenal glands produce the hormone aldosterone in excess. If this applies to you, the use of Valsartan Baldacci is not recommended.

If you have lost a large amount of fluid (dehydration) caused by diarrhoea, vomiting or high doses of diuretics.

If you are taking any of the following medicines to treat high blood pressure:

- An ACE inhibitor (e.g. enalapril, lisinopril, ramipril), in particular if you have kidney problems related to diabetes.
- Aliscireno
- If you are taking an ACE inhibitor together with certain medicines to treat heart failure, which are known as mineralcorticoid receptor antagonists (MRAs). (e.g. spironolactone, eplerenone) or beta-blockers (e.g. 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 the information under the heading "Do not take Valsartan Baldacci "

You need to tell your doctor if you think you are (or may be) pregnant. Valsartan Baldacci is not recommended in early pregnancy and cannot be taken if you are more than 3 months pregnant, because it can cause serious injury to your baby if it is used at that stage (see pregnancy section).

Other medicines and Valsartan Baldacci

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

The effect of treatment may be influenced if Valsartan Baldacci is taken with certain medicinal products. You may need to change the dose, take other precautions, or in some cases stop treatment with one of the medicines. This applies to both prescription and non-prescription medicines, in particular:

Other medicines used to lower blood pressure, such as diuretics, ACE inhibitors (such as enalapril, lisinopril, etc.) or aliskiren (see also information under the headings "Do not take Valsartan Baldacci" and "Warnings and precautions"). Medications that increase the amount of potassium in the blood. These include potassium supplements or saline substitutes containing potassium, potassium-sparing medications, and heparin. Certain types of painkillers called nonsteroidal anti-inflammatory drugs (NSAIDs). Some antibiotics (rifamycin group), a medicine used to prevent transplant rejection (cyclosporine) or antiretroviral medicines to treat HIV/AIDS infection (ritonavir). These medicines may enhance the effect of Valsartan Baldacci. Lithium, a medicine used to treat certain types of psychiatric illness.

In addition:

If you are being treated after a heart attack, combination with ACE inhibitors (a medicine for the treatment of a heart attack) is not recommended.

If you are being treated for heart failure, the triple combination of ACE inhibitors and other medicines to treat heart failure, known as mineralcorticoid receptor antagonists (MRAs) (e.g. spironolactone, eplerenone), or beta-blockers (e.g. metoprolol), is not recommended.

Pregnancy, breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or plan to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

Usually, your doctor will advise you to stop treatment with Valsartan Baldacci before you become pregnant, or as soon as you know you are pregnant, and will advise you to take another Valsartan Baldacci replacement medicine. Valsartan Baldacci is not recommended in early pregnancy and cannot be taken if you are more than 3 months pregnant because it can cause serious injury to your baby if it is used after the third month of pregnancy.

Tell your doctor if you are breastfeeding or are about to start breastfeeding. Valsartan Baldacci is not recommended for mothers who are breastfeeding and your doctor may choose another treatment for you if you wish to breastfeed, especially if your baby is newborn or premature.

Driving and using machines

Before driving a vehicle, using tools or machines, or performing other tasks that require concentration, make sure you know how you react to the effects of Valsartan Baldacci. As with other medicines used to treat high blood pressure, Valsartan Baldacci may, in rare cases, cause dizziness and affect the ability to concentrate.

3. How to Take Valsartan Baldacci

Take this medication exactly as directed by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure.

Always take this medicine as your doctor tells you to get the best results and reduce the risk of side effects. Often, patients with high blood pressure do not notice any signs of this problem. Many feel perfectly normal. It is therefore essential that you comply with the schedule of appointments with your doctor, even when you feel well.

Adult patients with high blood pressure: The recommended dose is 80 mg/day. In some cases, your doctor may prescribe larger doses (for example, 160 mg or 320

mg). You can also combine Valsartan Baldacci with another medicine (e.g. diuretics).

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

In patients weighing less than 35kg, the recommended dose is 40 mg valsartan once daily.

In patients weighing 35 kg or more, the recommended starting dose is 80 mg valsartan once daily.

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

Adult patients after a recent heart attack: after a heart attack, treatment is usually started within 12 hours, usually with a low dose of 20 mg twice daily. The 20 mg dose is obtained by dividing the 40 mg tablet. Your doctor will increase this dose gradually over several weeks to a maximum dose of 160 mg twice a day. The final dose depends on what each individual patient can tolerate.

Valsartan Baldacci can be given with another heart attack medicine, and it is up to your doctor to decide which treatment is right for you.

Adult patients with heart failure: treatment usually starts with 40 mg twice daily. Your doctor will increase the dose gradually over several weeks to a maximum dose of 160 mg twice a day. The final dose depends on what each individual patient can tolerate.

Valsartan Baldacci can be given with another medicine for heart failure, and it is up to your doctor to decide which treatment is right for you.

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

Take Valsartan Baldacci at about the same time every day.

If you take more Valsartan Baldacci 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 Baldacci

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for your next dose, do not take the missed dose.

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

Stop taking Valsartan Baldacci

Discontinuing treatment with Valsartan Baldacci may aggravate your condition. Do not stop taking the 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 require immediate medical attention:

You may experience symptoms of angioedema (a specific allergic reaction) such as swelling of the face, lips, tongue or throat, difficulty breathing or swallowing, hives (itchy rash), itching.

If you experience any of these symptoms, stop taking Valsartan Baldacci and contact your doctor immediately (see section 2 "Warnings and precautions")

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
Decreased renal function (signs of renal impairment)

Uncommon (may affect up to 1 in 100 people):
Angioedema (see section "Some symptoms require immediate medical attention")
Sudden loss of consciousness (syncope)
Feeling like you are spinning (vertigo)
Severely reduced kidney function (signs of acute renal failure)
Muscle spasms, abnormal heart rhythm (signs of hyperkalaemia)
Shortness of breath, difficulty breathing when lying down, swelling of the feet or legs (signs of heart failure)
Headache
Cough
Abdominal pain
Nausea
Diarrhea
Tiredness
Weakness

Not known (frequency cannot be estimated from the available data)
Bubble formation (sign of bullous dermatitis) allergic reactions may occur with rash, itching and hives (itchy rash), symptoms of fever, swelling of the joints, joint pain, muscle pain, swollen lymph nodes and/or flu-like symptoms (signs of serum sickness) red and purple spots, fever, itching (signs of inflammation of the blood vessels, also called vasculitis)
Abnormal bleeding or bruising (signs of thrombocytopenia)
Muscle pain (myalgia), fever, sore throat, or mouth ulcers due to infections (symptoms of low white blood cell levels, also called neutropenia)
Decreased hemoglobin level and decreased percentage of red blood cells in the blood (which can cause anaemia in severe cases)
Increased level of potassium in the blood (which can trigger muscle spasms and abnormal heart rhythm in severe cases)
Elevated liver function values (which may indicate liver damage), including an increased level of bilirubin in the blood (which can cause yellow skin and eyes in severe cases)
Increased level of nitrogen in blood urea and increased serum creatinine level (which may indicate, abnormal kidney function)
Low sodium level in the blood (which can cause tiredness, confusion, muscle spasms, and/or seizures in severe cases)

The frequency of certain side effects may vary depending on your condition. For example, side effects such as dizziness and decreased kidney function occurred 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, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report side effects directly to INFARMED, I.P. through the contacts below. By reporting side effects, you will be helping to provide more information about the safety of this medicine.

INFARMED, I.P.

Directorate of Drug Risk Management

Parque da Saúde de Lisboa, Av. Brazil 53

1749-004 Lisboa

Tel: +351 21 798 73 73

Drug Line: 800222444 (free of charge)

Fax: + 351 21 798 73 97

Website:

<http://extranet.infarmed.pt/page.seram.frontoffice.seramhomepage>

E-mail: farmacovigilancia@infarmed.pt

5. How to store Valsartan Baldacci

Do not store above 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 blister after EXP. The expiry date corresponds to the last day of the month indicated.

Do not dispose of any medicines in the sewer or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Package contents and other information

What Valsartan Baldacci contains

- The active substance is valsartan.

Each film-coated tablet contains 40 mg, 80 mg, 160 mg or 320 mg of valsartan.

- The other components are:

Core: microcrystalline cellulose, crospovidone, and magnesium stearate;

Coating: hypromellose 2910 (6 cps), titanium dioxide (E171), macrogol 8000, red iron oxide (E172) and yellow iron oxide (E172).

What Valsartan Baldacci looks like and contents of the pack

Valsartan Baldacci 40 mg film-coated tablets are yellow, round and convex and grooved on one side.

Valsartan Baldacci 80 mg film-coated tablets are pink, round and convex and grooved on one side.

Valsartan Baldacci 160 mg film-coated tablets are yellow to orange, oblong and convex and grooved on one side.

Valsartan Baldacci 320 mg film-coated tablets are brownish, oblong and convex and grooved on one side.

Valsartan Baldacci film-coated tablets are available in packs of 7, 10, 14, 28, 56, 60, 98 and 280 blister packs.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Baldacci - Portugal, S.A.

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Manufacturer

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