

Package leaflet: Information for the user

Valsartan + Hydrochlorothiazide Baldacci 80 mg/12.5 mg film-coated tablets
Valsartan + Hydrochlorothiazide Baldacci 160 mg/12.5 mg film-coated tablets
Valsartan + Hydrochlorothiazide Baldacci 160 mg/25 mg film-coated tablets
Valsartan + Hydrochlorothiazide Baldacci 320 mg/12.5 mg film-coated tablets
Valsartan + Hydrochlorothiazide Baldacci 320 mg/25 mg film-coated tablets
Valsartan+hydrochlorothiazide

Read all of 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 may be harmful to them even if they show the same signs of illness.
- If you experience any side effects, talk to your doctor or pharmacist. Including possible undesirable effects not listed in this leaflet. See section 4.

What's in this leaflet:

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

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

Valsartan + Hydrochlorothiazide Baldacci film-coated tablets contain two active substances called valsartan and hydrochlorothiazide. Both substances help control high blood pressure (hypertension).

Valsartan belongs to a class of medicines known as "angiotensin II receptor antagonists" that 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 works by blocking the effect of angiotensin II. Consequently, blood vessels dilate and blood pressure decreases.

Hydrochlorothiazide belongs to a group of drugs called thiazide diuretics. Hydrochlorothiazide increases urine flow, which also lowers blood pressure.

Valsartan + Hydrochlorothiazide Baldacci is used to treat high blood pressure when it is not adequately controlled with a substance alone.

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 a 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 conditions.

2. Or what do you need to know before taking Valsartan + Hydrochlorothiazide Baldacci

Do not take Valsartan + Hydrochlorothiazide Baldacci

If you are allergic (hypersensitive) to valsartan, hydrochlorothiazide, sulphonamide derivatives (substances chemically related to hydrochlorothiazide) or any of the other ingredients of this medicine (mentioned in section 6).

If you are more than 3 months pregnant (it is also best to avoid Valsartan + Hydrochlorothiazide Baldacci in early pregnancy – see pregnancy section).

If you suffer from severe liver disease, destruction of the bile ducts within the liver (biliary cirrhosis), leading to accumulation of bile in the liver (cholestasis)

If you suffer from severe kidney disease.

If you are unable to produce urine (anuria).

If you are on dialysis.

If the potassium or sodium levels in the blood are lower than normal, or if the calcium level in the blood is higher than normal despite treatment.

If you have gout.

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 + Hydrochlorothiazide Baldacci.

Warnings and precautions

Talk to your doctor or pharmacist before taking Valsartan + Hydrochlorothiazide Baldacci

. if you have had skin cancer or if you develop an unexpected skin lesion during treatment. Treatment with hydrochlorothiazide, particularly long-term high-dose use, may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer). Protect your skin from sun exposure and ultraviolet radiation while taking Valsartan + Hydrochlorothiazide Baldacci

If you are taking potassium-sparing medicines, potassium supplements or saline substitutes that contain potassium, or other medicines that increase the amount of potassium in the blood, such as heparin. Your doctor may need to check the level of potassium in your blood regularly.

If you have low potassium levels in your blood.

If you have severe diarrhoea or vomiting.

If you are taking high doses of diuretics.

If you suffer from severe heart disease.

If you suffer from heart failure or have suffered a heart attack. Follow your doctor's instructions about the starting dose carefully. Your doctor may also check your kidney function.

If you suffer from narrowing of the renal artery.

If you have recently undergone a kidney transplant.

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

If you suffer from kidney or liver disease.

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 + Hydrochlorothiazide Baldacci, stop taking Valsartan + Hydrochlorothiazide Baldacci immediately and do not take it again. See also section 4 "Undesirable effects".

If you have fever, rash and joint pain, which may be symptoms of systemic lupus erythematosus (SLE, an autoimmune disease).

If you have diabetes, gout, high cholesterol or triglyceride levels in your blood.
If you have had allergic reactions with other blood pressure-lowering drugs in this class (angiotensin II receptor antagonists) or if you have an allergy or asthma.
If you experience a decrease in vision or eye pain. These may be symptoms of fluid build-up in the vascular layer of the eye (choroidal effusion) or an increase in pressure in the eye and may occur within hours up to a week after taking Valsartan + Hydrochlorothiazide Baldacci. This can lead to permanent vision loss if left untreated.
If you have suffered an allergy to penicillin or sulfonamides, you may be at higher risk of developing this condition.

If you are taking any of the following medicines to treat high blood pressure:
- an ACE inhibitor (e.g. enalapril, lisinopril, ramipril), particularly if you have kidney problems related to diabetes.
- Aliscireno.

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

See also the information under the heading "Do not take Valsartan + Hydrochlorothiazide Baldacci"

Valsartan + Hydrochlorothiazide Baldacci may cause increased skin sensitivity to the sun

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

You need to tell your doctor if you think you are (or may be) pregnant. Valsartan + Hydrochlorothiazide 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 + Hydrochlorothiazide 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 + Hydrochlorothiazide 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 the following medicines:

Lithium, a medicine used to treat certain types of psychiatric illness

Medications or substances that can increase the amount of potassium in the blood, including potassium supplements or potassium-containing salt substitutes, potassium-sparing medications, and heparin.

Medications that can reduce the amount of potassium in the blood, such as diuretics, corticosteroids, laxatives, carbenoxolone, amphotericin, or penicillin G.

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 + Hydrochlorothiazide Baldacci

Medications that can induce "torsades de pointes" (irregular heartbeat), such as antiarrhythmics (drugs used to treat heart problems) and some antipsychotics.

Medicines that can reduce the amount of sodium in the blood, such as antidepressants, antipsychotics, antiepileptics

Gout treatment medications, such as allopurinol, probenecid, sulfinpyrazone
Vitamin D Supplements and Calcium Supplements
Medicines for the treatment of diabetes (oral medicines such as metformin or insulins)
Other medicines used to lower blood pressure including methyldopa, ACE inhibitors (such as enalapril, lisinopril, etc.) or aliskiren (see also information under the headings "Do not take Valsartan + Hydrochlorothiazide Baldacci" and "Warnings and precautions with Valsartan + Hydrochlorothiazide Baldacci").
Medicines to increase blood pressure, such as noradrenaline or adrenaline, digoxin, or other digitalis (medicines used to treat heart problems).
Medicines that raise blood sugar levels, such as diazoxide or beta blockers
Cytotoxic medicines (used to treat cancer) such as methotrexate or cyclophosphamide
Analgesics, such as nonsteroidal anti-inflammatory agents (NSAIDs), including selective cyclooxygenase 2 inhibitors (Cox-2 inhibitors) and acetylsalicylic acid > 3g
Muscle relaxant medications such as tubocurarine
Anticholinergic medicines (medicines used to treat a variety of ailments, such as gastrointestinal cramps, bladder spasms, asthma, motion sickness, muscle spasms, Parkinson's disease and as an aid to anaesthesia)
Amantadine (a medicine used to treat Parkinson's disease also used to treat or prevent certain diseases caused by viruses)
Cholestyramine and colestipol (medicines used mainly to treat high levels of lipids in the blood)
Cyclosporine, a drug used in organ transplantation to prevent organ rejection
Alcohol, sleeping pills and anesthetics (drugs with an analgesic or sedative effect used, for example, during surgery)
Iodinated contrast media (agents used for imaging)

Taking Valsartan + Hydrochlorothiazide Baldacci with food, drink and alcohol

Avoid drinking alcoholic beverages until you have talked to your doctor. Alcohol can cause your blood pressure to drop further, or it can increase your risk of getting dizzy or fainting.

Pregnancy and breast-feeding

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 + Hydrochlorothiazide Baldacci before you become pregnant, or as soon as you know you are pregnant, and will advise you to take another Valsartan + Hydrochlorothiazide Baldacci replacement medicine. Valsartan + Hydrochlorothiazide 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 + Hydrochlorothiazide Baldacci is not recommended for breastfeeding mothers 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 + Hydrochlorothiazide Baldacci. As with other medicines used to treat high blood

pressure, Valsartan + Hydrochlorothiazide Baldacci may occasionally cause dizziness and impair the ability to concentrate.

3. How to take Valsartan + Hydrochlorothiazide 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. This will help you 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.

Your doctor will tell you exactly how many Valsartan + Hydrochlorothiazide Baldacci tablets you should take. Depending on your response to treatment, your doctor may prescribe a higher or lower dose.

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

Do not change the dose or stop taking the tablets without consulting your doctor.

The drug should always be taken at the same time each day, usually in the morning.

You can take Valsartan + Hydrochlorothiazide Baldacci with or without food.

Swallow the tablets with a glass of water.

If you take more Valsartan + Hydrochlorothiazide Baldacci 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.

Case you have been left taking Valsartan + Hydrochlorothiazide 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.

Do you stop taking Valsartan + Hydrochlorothiazide Baldacci

Discontinuing treatment with Valsartan + Hydrochlorothiazide Baldacci may worsen your blood pressure. 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 undesirable effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some symptoms can be severe and require immediate medical attention:

Frequency 'not known': Skin and lip cancer (non-melanoma skin cancer)

You should see your doctor immediately if you have symptoms of angioedema, such as:

Swelling of the face, tongue, or pharynx

Difficulty swallowing

Rash and difficulty breathing

Severe skin disease causing skin rashes, redness, blisters on the lips, eyes, or mouth, peeling of the skin, fever (toxic epidermal necrolysis)

Decreased vision or eye pain due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma).

Fever, sore throat, more common infections (agranulocytosis)

These undesirable effects are very rare or of unknown frequency

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

Undesirable effects include:

Uncommon (may affect up to 1 in 100 people):

Cough

Low blood pressure

Hollow head feeling

Dehydration (with symptoms of thirst, dry mouth and tongue, infrequent urination, dark-coloured urine, dry skin)

Muscle pain

Tiredness

Tingling or numbness

Disturbance of vision

Noises (e.g. wheezing, ringing) in the ears

Very rare (may affect up to 1 in 10,000 people):

Silly

Diarrhoea

Joint pain

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

Difficulty breathing

Marked reduction in urine flow

Low sodium level in the blood (can trigger tiredness, confusion, muscle twitching, and/or seizures in severe cases)

Low level of potassium in the blood (sometimes with muscle weakness, cramps, heart arrhythmias)

Low level of white blood cells in the blood (with symptoms such as fever, skin infections, sore throat or mouth ulcers due to infections, weakness)

Increased level of bilirubin in the blood (which can, in severe cases, cause yellow skin and eyes)

Increased level of urea and creatinine in the blood (which may be suggestive of altered kidney function)

Increased level of uric acid in the blood (which can, in severe cases, cause gout)

Syncope (fainting)

The following undesirable effects have been reported with medicinal products containing valsartan or hydrochlorothiazide alone:

Valsartan

Uncommon (may affect up to 1 in 100 people):

Spinning sensation

Dor abdominal

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

Blistering (sign of bullous dermatitis)

Itchy or non-itchy skin rash associated with any of the following signs or symptoms: fever, joint pain, muscle pain, swollen lymph nodes, and/or flu-like symptoms

Rash, purplish-red spots, fever, itching (signs of inflammation of the blood vessels)

Decreased level of platelets in the blood (sometimes accompanied by abnormal bleeding or bruising)

Increased level of potassium in the blood (sometimes with muscle spasms, abnormal heart rhythm)

Allergic reactions (with symptoms such as rash, itching, hives (itchy rash), difficulty breathing or swallowing, dizziness)

Swelling especially of the face and throat, rash, itching

Elevation of liver function values

Decreased haemoglobin level and decreased percentage of red blood cells in the blood (which can both, in rare cases, cause anaemia).

Renal insufficiency

Low sodium level in the blood (which can cause tiredness, confusion, muscle spasms, and/or seizures in severe cases)

Hydrochlorothiazide

Very common (may affect more than 1 in 10 people):

Low level of potassium in the blood

Increased blood lipids

Common (may affect up to 1 in 10 people):

Low level of sodium in the blood

Low level of magnesium in the blood

High level of uric acid in the blood

Itchy skin rash and other forms of rash

Loss of appetite

Nausea and light vomiting

Dizziness, fainting when standing up

Inability to get or maintain an erection

Rare (may affect up to 1 in 1,000 people):

Swelling and blistering of the skin (due to increased sensitivity to the sun)

High level of calcium in the blood

High blood sugar

Sugar in the urine

Worsening of the metabolic status of diabetes

Constipation, diarrhoea, gastrointestinal discomfort, liver disorders, which may occur in conjunction with yellow skin and eyes
Irregular heartbeat
Headache
Sleep disturbances
Sadness and depression)
Low levels of platelets in the blood (sometimes with bleeding or bruising on the skin)
Silly
Tingling or numbness
Vision disorders

Very rare (may affect up to 1 in 10,000 people):

Inflammation of the blood vessels with symptoms such as rash, purplish-red spots, fever (vasculitis)
Rash, pruritus, hives (itchy rash), difficulty breathing or swallowing, dizziness (hypersensitivity reactions)
Severe skin disease causing skin rashes, blisters on the lips, eyes, or mouth, peeling of the skin, fever (toxic epidermal necrolysis)
Facial rash, joint pain, muscle pain, fever (cutaneous lupus erythematosus)
Severe pain in the upper abdomen (pancreatitis)
Difficulty breathing with fever, cough, wheezing, shortness of breath (difficulty breathing including pneumonitis and pulmonary edema)
Paleness, tiredness, lack of RA, urinary scarcity (hemolytic anemia)
Fever, sore throat or canker sores due to infections (agranulocytosis)
Confusion, tiredness, muscle twitching and spasming, rapid breathing (hypochloraemic alkalosis)

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

Weakness, frequent infections and bruising (aplastic anaemia)
Severely decreased urine output (possible signs of kidney disease or kidney failure)
Skin rashes, redness, blisters on the lips, eyes, or mouth, peeling of the skin, fever (possible signs of erythema multiforme)
Muscle spasm
Fever (pyrexia)
Fraqueness (asthenia)

Reporting of undesirable effects

If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist or nurse. You can also report undesirable effects directly to INFARMED, I.P. through the contacts below. By reporting side effects, you are helping to provide more information about the safety of this medicine.

Website: <http://www.infarmed.pt/web/infarmed/submissaoram> (preferencialmente) ou através dos seguintes contactos:

Direção de Gestão do Risco de Medicamentos
Parque da Saúde de Lisboa, Av. Brasil 53
1749-004 Lisboa
Tel: +351 21 798 73 73
Linha do Medicamento: 800222444 (gratuita)
E-mail: farmacovigilancia@infarmed.pt

5. How to store Valsartan + Hydrochlorothiazide 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 + Hydrochlorothiazide Baldacci contains

The active substances are valsartan and hydrochlorothiazide.

Each film-coated tablet contains 80 mg, 160 mg or 320 mg of valsartan, respectively, and 12.5 mg or 25 mg of hydrochlorothiazide, respectively.

Other ingredients are: microcrystalline cellulose, crospovidone and magnesium stearate. The tablet coating contains: hypromellose 6 cps, titanium dioxide (E171), talc, macrogol 8000, red iron oxide (E172) and yellow iron oxide (E172).

What Valsartan + Hydrochlorothiazide Baldacci looks like and contents of the pack

Valsartan + Hydrochlorothiazide Baldacci 80 mg + 12.5 mg tablets are oblong and convex, pink in colour.

Valsartan + Hydrochlorothiazide Baldacci 160 mg + 12.5 mg tablets are red, oblong and convex, grooved on one side.

Valsartan + Hydrochlorothiazide Baldacci 160 mg + 25 mg tablets are orange in colour, oblong and convex, grooved on one side.

Valsartan + Hydrochlorothiazide Baldacci 320 mg + 12.5 mg tablets are oblong and convex, light pink in color.

Valsartan + Hydrochlorothiazide Baldacci 320 mg + 25 mg tablets are oblong and convex, light yellow in colour.

The tablets are available in blister packs of 10, 14, 28, 56 or 280 tablets.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

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