

Vicapril

Comprimido de Captopril BP 25 mg

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 symptoms are the same as yours.
- If you get any side effects, including any not listed in this leaflet, talk to your doctor or pharmacist. See section 4.

What's in this leaflet

1. What Captopril Tablets are and what they are used for
2. What you need to know before you take Captopril Tablets
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1. What are Captopril Tablets and what are they used for?

Captopril Tablets belong to a group of medicines known as angiotensin-converting enzyme (ACE) inhibitors, the enzyme involved in the conversion of angiotensin I to angiotensin II. Angiotensin II is a substance produced in the body that binds to receptors in blood vessels, causing them to narrow, which leads to increased blood pressure. Captopril Tablets are used to reduce high blood pressure (hypertension) or to help the heart pump blood to all parts of the body in patients with chronic heart failure. It is also used to treat people after a myocardial infarction to improve survival and reduce subsequent heart problems. Captopril Tablets may be used to treat kidney disease in patients with diabetes.

2. What you need to know before taking Captopril Tablets

Do not take Captopril Tablets

- if you are allergic to Captopril or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic to another angiotensin-converting enzyme inhibitor
- if you are more than three months pregnant. (It is also preferable not to take Captopril Tablets in early pregnancy - see section "Pregnancy")
- if you have a history of angioedema or angioedema associated with previous treatment with an ACE inhibitor (ask your doctor if you have any questions)
- if you have diabetes or impaired kidney function and are being treated with a medicine containing aliskiren to lower blood pressure
- if you have taken or are taking sacubitril/valsartan, a medicine used in adults to treat a type of long-term (chronic) heart failure, because it increases the risk of angioedema (rapid swelling under the skin in an area such as the throat)
- if you are taking any of the following medicines, the risk of angioedema may be increased:
 - racecadotril, a medicine used to treat diarrhea; medicines belonging to the class of mTOR inhibitors used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus) a
 - vildagliptin, a medicine Used to treat diabetes.

If you are in one of the above situations, inform your doctor or pharmacist and ask for their advice.

Warnings and precautions

Talk to your doctor or pharmacist before taking Captopril Tablets. If you are taking any of the following medicines to treat high blood pressure:

- an angiotensin II receptor antagonist (ARB) (also known as sartans, for example valsartan, telmisartan, irbesartan), particularly if you have kidney problems related to diabetes
- aliskiren.

Your doctor may check your kidney function, blood pressure and the amount of electrolytes (for example, potassium) in your blood at regular intervals. See also the information under the heading "Do not take Captopril Tablets."

Certain health conditions you may have, or have had in the past, require special attention before taking or while taking Captopril Tablets. Therefore, before taking this medication, you must inform your doctor if you suffer from: prolonged vomiting or diarrhea, kidney problems, heart problems, liver problems, or diabetes.

If you are scheduled to undergo surgery or receive anesthetics, you must inform your doctor that you are taking Captopril Tablets.

ACE inhibitors should not be used in combination with angiotensin II receptor blockers in patients with diabetic nephropathy.

You must inform your doctor if you think you are (or might be) pregnant. Captopril Tablets is not recommended during early pregnancy and must not be taken after the third month of pregnancy, as it may be severely harmful to the baby if used from that point onward.

Children

Cases of excessive, prolonged, and unpredictable decreases in blood pressure, as well as associated complications—including decreased urine output and seizures—have been reported.

Other medicines and Captopril Tablets

Inform your doctor or pharmacist if you are taking, have recently taken, or intend to take any other medicines:

potassium supplements (including salt substitutes), potassium-sparing diuretics, and other medicines that may increase the amount of potassium in your blood (for example, trimethoprim and co-trimoxazole for bacterial infections; cyclosporine, an immunosuppressant used to prevent organ transplant rejection; and heparin, a medicine used to thin the blood to prevent clots). **Certain special precautionary measures (e.g., blood tests) may be recommended** if you are taking potassium-sparing diuretics, potassium supplements, salt substitutes containing potassium, lithium compounds, medications for the treatment of gout, or medications for the control of heart rhythm or diabetes (oral medications or insulin).

Your doctor may need to adjust your dose and/or take other precautions:

- if you are taking an angiotensin II receptor antagonist (ARB) or aliskiren (see also the information under the headings "Do not take Captopril Tablets" and "Warnings and precautions")
- if you are taking medications most frequently used to prevent organ transplant rejection (sirolimus, everolimus, and other medications belonging to the class of mTOR inhibitors). Refer to the "Warnings and precautions" section.

It is also important that your doctor knows if you are taking other medications to lower blood pressure, steroids, antineoplastics, analgesics, arthritis medications, antidepressants, or antipsychotics.

As with other medications used to lower blood pressure, the effect of Captopril may be reduced when taken concurrently with non-steroidal anti-inflammatory drugs.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding, if you think you may be pregnant, or if you are planning to become pregnant, consult your doctor or pharmacist before taking this medication.

Pregnancy

You must inform your doctor if you think you are (or might be) pregnant. Your doctor will usually advise you to stop taking Captopril Tablets before becoming pregnant or as soon as you confirm you are pregnant, and to switch to a different medication instead of Captopril Tablets. Captopril Tablets are not recommended during the first trimester of pregnancy and must not be taken after the third month of pregnancy, as they can cause serious harm to the baby if used during this period.

Breastfeeding

You must inform your doctor if you are breastfeeding or intend to start breastfeeding. Breastfeeding is not recommended for

newborns (during the first few weeks after birth)—and especially for premature babies—while the mother is taking Captopril Tablets. In the case of an older infant, your doctor should advise you regarding the benefits and risks of taking Captopril Tablets while breastfeeding, compared to other medications.

Driving vehicles and operating machinery

The ability to drive or operate machinery may be impaired—for instance, at the start of treatment, when the dosage is changed, or when used in combination with alcohol—though these effects depend on individual susceptibility. If you experience these effects, you should consult your doctor before attempting such activities.

Captopril Tablets contain lactose

If your doctor has informed you that you have an intolerance to certain sugars, please contact them before taking this medication.

3. How to take Captopril Tablets

Take this medication exactly as directed by your doctor. Consult your doctor or pharmacist if you have any questions.

Captopril tablets may be taken before, during, or after meals. The tablets should be taken with water, and, if possible, you should take your daily dose at the same time every day.

In the treatment of hypertension, the recommended initial dose is 12.5 to 25 mg twice daily. Your doctor may gradually increase the dose up to 100–150 mg per day as necessary to achieve the desired blood pressure, or may combine it with another antihypertensive medication.

The doctor may prescribe a lower initial dose for elderly patients or patients with kidney problems.

When Captopril Tablets are used to treat patients with heart failure, the recommended initial dose is 6.25 to 12.5 mg, taken two or three times daily. The doctor may gradually increase the dose up to 150 mg per day.

When used following a myocardial infarction (heart attack), the recommended test dose is 6.25 mg; the dose will subsequently be increased by the doctor up to a maximum of 150 mg per day.

In the treatment of kidney disease in patients with diabetes, the recommended dose of Captopril Tablets is 75 to 100 mg per day.

Use in Children

In children, the initial dose is 0.3 mg/kg of body weight, generally administered 3 times daily; the dose and the interval between doses are adjusted by the doctor depending on the patient's response.

It is important that you continue taking Captopril Tablets until your doctor gives you other instructions.

The 25 mg Captopril Tablet can be divided into equal doses.

If you take more Captopril Tablets than you should

If you accidentally take too many tablets, or if a child swallows some tablets, you should contact a doctor immediately.

If you forget to take Captopril Tablets

If you accidentally miss a dose, take the next dose as usual. Do not take a double dose to make up for a forgotten dose.

If you still have questions regarding the use of this medication, talk to your doctor or pharmacist.

4. Possible side effects

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

Side effects associated with Captopril are generally rare and transient. They are usually mild and typically do not require discontinuation of treatment.

Symptoms or sensations frequently reported (may affect more than

1 in 10 people) by patients taking Captopril include: sleep disturbances, loss of taste, dizziness, dry cough, dyspnea (shortness of breath), nausea, vomiting, gastric irritation, abdominal pain, diarrhea, constipation, dry mouth, dyspepsia (indigestion), pruritus (itching) with or without rash, rash, and alopecia (hair loss).

Uncommon side effects (may affect up to 1 in 100 people) include: decreased appetite, headache, paresthesia (tingling or prickling sensations), tachycardia, arrhythmia, angina pectoris, palpitations, hypotension (low blood pressure), Raynaud's syndrome, flushing, pallor, orthostatic hypotension, angioedema, chest pain, fatigue, malaise, and asthenia (weakness). Rare side effects (may affect up to 1 in 1,000 people) included: stomatitis/apthous ulceration, angioedema of the small intestine.

Very rare side effects (may affect up to 1 in 10,000 people) included: neutropenia/agranulocytosis, pancytopenia (particularly in patients with renal dysfunction), anemia (including aplastic and hemolytic), thrombocytopenia, eosinophilia, autoimmune diseases, hyperkalemia, hyponatremia, confusion, depression, cerebrovascular accident (stroke), cerebral vascular insufficiency, syncope, blurred vision, bronchospasm, rhinitis, eosinophilic pneumonia, glossitis, pancreatitis, impaired liver function and cholestasis (including jaundice), hepatitis (including necrosis), elevated liver enzymes, increased blood bilirubin, increased transaminase, increased blood alkaline phosphatase, urticaria, Stevens-Johnson syndrome, erythema multiforme, photosensitivity, erythroderma, pemphigoid reactions, exfoliative dermatitis, myalgia, arthralgia, nephrotic syndrome, erectile dysfunction, gynecomastia, fever, proteinuria, eosinophilia, increased BUN, serum creatinine, and serum bilirubin, decreased platelet count, positive antinuclear antibody titers, and increased erythrocyte sedimentation rate.

If you notice any signs of infection (e.g., sore throat, fever), as well as other abnormal symptoms or sensations while taking Captopril Tablets, you should inform your doctor or pharmacist and seek their advice.

If any of the side effects worsen, or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist.

5. How to store Captopril Tablets

Store below 30°C in a dry place. Protect from light.

Manufactured by:

