**Captopril 12.5 mg, 25mg and 50mg tablets**

**What is captopril and what is it used for?**

Captopril belongs to a certain group of blood pressure-lowering medicines called ACE inhibitors.

Captopril is used:

* If you have high blood pressure.
* If your heart does not pump properly (this is called heart failure or decompensatio cordis).
* After having a heart attack.
* If you are a diabetic and, as a result, have kidney abnormalities.

**When should you not use this medicine or take extra precautions?**

**When should you not use this medicine?**

You should not use Captopril tablets if:

* You are allergic to any of the substances present in this medicine. You can find these substances in section 6.
* You are allergic to other medicines of this type (ACE inhibitors).
* You have experienced sudden swelling of the skin and mucous membranes (such as throat or tongue), difficulty breathing, and/or itching and skin rash (angioedema) due to previous use of ACE inhibitors, hereditary factors, or unknown cause.
* You are more than 3 months pregnant. (It is also advisable to avoid Captopril at the beginning of pregnancy - see 'pregnancy').
* You have diabetes or kidney impairment and are being treated with a blood pressure-lowering medicine containing aliskiren.
* If you are using or have used sacubitril/valsartan, a medication used for the treatment of a type of chronic heart failure in adults, the risk of angioedema (rapid swelling beneath the skin, such as in the throat) is increased.

**When should you take extra precautions with this medicine?**

**Contact your doctor or pharmacist before using this medicine.**

**This medicine should be used with caution by patients:**

* Inform your doctor if you think you are pregnant or planning to become pregnant. The use of Captopril is not recommended during early pregnancy and should not be used if you are more than 3 months pregnant, as it may have severe adverse effects on the baby during this stage of pregnancy (see also 'pregnancy').
* If your blood pressure drops significantly (hypotension). This may manifest as dizziness or lightheadedness. These symptoms generally disappear when you lie down. As with any blood pressure-lowering medication, a significant drop in blood pressure in patients with heart and vascular diseases can increase the risk of a heart attack or stroke.
* If you experience sudden swelling of the skin and mucous membranes (such as throat or tongue), difficulty breathing, and/or itching and skin rash, often as an allergic reaction (angioedema). In this case, you should immediately consult your doctor.
* If your skin or eyes turn yellow (jaundice). In this case, you should immediately consult your doctor if your kidney function is impaired or if you have diabetes mellitus (see also later in this section), or if you are concurrently using other potassium-sparing or potassium-raising medications (such as certain diuretics, heparin, and salt substitutes). The potassium level in your blood should be regularly monitored.
* If you have certain heart and vascular conditions (aortic and mitral stenosis, obstructive hypertrophic cardiomyopathy, and cardiogenic shock).
* If you have collagen vascular disease of the blood vessels.
* If you are being treated with immunosuppressants (medications that suppress the immune system) or with allopurinol (a medication for gout) or procaïnamide (a medication for cardiac arrhythmias). You have an increased risk of infections due to a possible deficiency of white blood cells (agranulocytosis and neutropenia). If you experience sore throat or fever, you should notify your doctor.
* If you are being treated for insect hypersensitivity (e.g., bees, wasps).
* If your blood is being purified through a machine (hemodialysis).
* If you are undergoing surgery or need to be anesthetized.
* If you have diabetes and are being treated for it. The amount of sugar in your blood should be monitored. It may be necessary to adjust the dosage of your antidiabetic medications.
* If you have dark skin color. Captopril may be less effective in such cases.
* If you are using any of the following medications, the risk of angioedema may be increased: Racecadotril, a medication for the treatment of diarrhea.
* Medications used to prevent organ transplant rejection and in cancer treatment (such as temsirolimus, sirolimus, everolimus).
* Vildagliptin, a medication for the treatment of diabetes.
* If you are taking any of the following medications for the treatment of high blood pressure:An angiotensin II receptor antagonist (ARB) (also known as sartans, such as valsartan, telmisartan, irbesartan), particularly if you have diabetes-related kidney problems.
* Aliskiren.

Your doctor may regularly check your kidney function, blood pressure, and electrolyte levels (such as potassium) in your blood.

Consult your doctor if any of the above warnings apply to you or have applied in the past.

**Are you taking any other medications?**In addition to Captopril Mylan, are you currently taking any other medications, or have you taken them recently, or is there a possibility that you will be taking other medications in the near future? Inform your doctor or pharmacist about that.

Your doctor may adjust your dose and/or take other precautions. Inform your doctor if you are using any of the following medications:

* Sacubitril/valsartan (used in patients with heart failure). See section "When should you not use this medicine?".
* Racecadotril (used in patients with acute diarrhea). See section "When should you take extra precautions with this medicine?".
* Medications commonly used to prevent organ transplant rejection (sirolimus, everolimus, and other medications belonging to the class of mTOR inhibitors). See section "When should you take extra precautions with this medicine?".
* Potassium supplements (including salt substitutes), potassium-sparing diuretics, and other medications that may increase the potassium level in your blood (e.g., trimethoprim and co-trimoxazole for bacterial infections; cyclosporine, an immunosuppressant used to prevent organ transplant rejection; and heparin, a medication used to thin the blood to prevent blood clot formation).
* If Captopril is taken immediately after certain other diuretics (thiazide or loop diuretics), there is an increased risk of significant blood pressure drop. Your treating doctor will take this into account.
* Captopril should be administered with caution along with medications for chest pain (nitroglycerin or other nitrates).
* Concurrent administration of Captopril with certain antidepressant medications (tricyclic antidepressants) or antipsychotic medications can result in a significant drop in blood pressure, such as upon quickly changing from a sitting or lying position (orthostatic hypotension). This may manifest as dizziness or lightheadedness. These symptoms generally disappear when you lie down.
* If Captopril is concurrently administered with medications that suppress the immune system (immunosuppressants) or with allopurinol (a medication for gout) or procaïnamide (a medication for cardiac arrhythmias) or with cytostatics (medications for cancer), you have an increased risk of infections due to a possible deficiency of white blood cells. If you experience sore throat or fever, you should notify your doctor.
* The effectiveness of Captopril may be reduced by concurrent use of medications that have a stimulating effect on a specific part of the nervous system (sympathomimetics). Your doctor will carefully monitor your condition.
* Concurrent use of medications for diabetes may require a dosage adjustment of these medications.
* If you are taking lithium, exercise caution. In combination with Captopril Mylan, the amount of lithium in your blood may increase, which can have harmful effects.
* The effectiveness of Captopril may be reduced by concurrent use of certain pain medications with anti-inflammatory and antipyretic effects (prostaglandin synthetase inhibitors). Moreover, these medications enhance each other's potential to increase the potassium level in the blood.
* If you are taking an angiotensin II receptor antagonist (ARB) or aliskiren (see also information in the sections "When should you not use this medicine?" and "When should you take extra precautions with this medicine?").

**Pregnancy and breastfeeding**Are you pregnant, do you think you may be pregnant, planning to become pregnant, or breastfeeding? Please consult your doctor or pharmacist before using this medicine.

**Pregnancy**Inform your doctor if you think you are pregnant or planning to become pregnant. Usually, your doctor will advise you to discontinue the use of Captopril before you become pregnant or as soon as you know that you are pregnant, and use an alternative medication instead. Captopril is not recommended for use during early pregnancy and should not be used if you are more than 3 months pregnant, as it may have severe adverse effects on the baby when used from the third month of pregnancy onwards.

**Breastfeeding**Inform your doctor if you are breastfeeding or planning to start breastfeeding. Breastfeeding newborn babies (during the first weeks after birth), especially premature babies, is not recommended during the use of Captopril Mylan. If the child is older, your doctor should advise you on the benefits and risks of using Captopril during breastfeeding compared to other treatments.

**Driving and using machinery**Depending on individual sensitivity, the ability to drive and operate machinery may be impaired.

**Captopril contains lactose and sodium:** If your doctor has informed you that you have an intolerance to certain sugars, please contact your doctor before taking this medication.

This medicine contains less than 1 mmol of sodium (23 mg) per tablet, essentially making it 'sodium-free'.

**How to use this medicine?**Always use this medicine exactly as your doctor or pharmacist has instructed you. If you are unsure about the correct usage, please contact your doctor or pharmacist.

**Dosage:** Your doctor will determine the dosage of Captopril Mylan, which depends on your condition.

A dosage of 6.25 mg is not possible with Captopril Mylan. You should use other appropriate formulations for this dosage.

**Use in high blood pressure:** For elevated blood pressure, the initial dose is 25-50 mg per day. Depending on the effect, your doctor may increase this dose up to a maximum of 150 mg per day. Captopril should generally be taken twice a day for high blood pressure. Once-daily dosing may be suitable when Captopril is used in combination with other blood pressure-lowering medications. If you have low blood volume (hypovolemia), high blood pressure in the kidneys (renovascular hypertension), or insufficient pumping power of the heart (heart failure or decompensatio cordis), it is better to start with once-daily 6.25 mg or 12.5 mg. The dosage can be gradually increased to 50 mg per day divided into one or two doses, and if necessary, up to 100 mg per day divided into one or two doses.

**Use in heart failure:** For heart failure, start with two or three times daily 6.25 mg to 12.5 mg. Your doctor may gradually increase this dosage up to a maximum of 150 mg per day divided into multiple doses.

**After a heart attack:** Initial treatment: After a heart attack, the initial treatment should begin as soon as possible in the hospital, with a dose of 6.25 mg, followed by a dose of 12.5 mg 2 hours later, and a dose

**Possible Side Effects**Like any medicine, this medicine can have side effects, although not everyone experiences them.

* The frequencies of the side effects mentioned below are categorized as follows:
* Very common: affects more than 1 in 10 users
* Common: affects less than 1 in 10 users
* Uncommon: affects less than 1 in 100 users
* Rare: affects less than 1 in 1,000 users
* Very rare: affects less than 1 in 10,000 users

Not known: frequency cannot be determined from the available data.

Side effects reported as a result of treatment with Captopril or other ACE inhibitors include:

**Blood and lymphatic system:** Very rare: deficiency of white blood cells accompanied by sudden high fever, severe sore throat, mouth ulcers, and increased susceptibility to infections (neutropenia/agranulocytosis); anemia (pancytopenia, including aplastic and hemolytic anemia), decreased platelet count (thrombocytopenia), lymph node disorders (lymphadenopathy), increase in certain blood cells accompanied by generalized lymph node swelling (eosinophilia), autoimmune diseases caused by the production of antibodies against body tissues (autoimmune diseases).

**Digestive system**Rare: loss of appetite (anorexia).
Very rare: high potassium levels in the blood, sometimes resulting in muscle cramps, diarrhea, nausea, dizziness, headache (hyperkalemia), low blood sugar levels accompanied by feelings of hunger, sweating, dizziness, palpitations (hypoglycemia).

**Psychiatric disorders**Common: sleep disorders.
Very rare: confusion, depression.

**Nervous system**Common: loss of taste, dizziness.
Rare: drowsiness, headache, and perception of tingling, itching, or tingling without any apparent cause (paresthesia).
Very rare: stroke/cerebral infarction, also known as a stroke or brain hemorrhage (cerebrovascular accident (CVA)).

**Eyes:** Very rare: blurred vision.

**Heart:** Uncommon: accelerated heartbeat (tachycardia or tachyarrhythmia), chest pain (angina pectoris), palpitations.

Very rare: cardiac arrest, a heart condition that can be accompanied by accelerated heartbeat, sweating, shortness of breath, and sometimes loss of consciousness (cardiogenic shock).

**Blood vessels:** Uncommon: low blood pressure (hypotension), paleness or bluish discoloration of the fingers or toes (Raynaud's syndrome), flushing, pallor.

**Respiration:** Common: dry, irritating (non-productive) cough, difficulty breathing (dyspnea).
Very rare: tightness of the chest due to muscle spasms of the airways (bronchospasm), inflammation of the nasal mucosa characterized by nasal congestion, sneezing, and discharge (rhinitis), inflammation of parts of the lungs (allergic alveolitis/eosinophilic pneumonia).

**Stomach and intestines**Common: nausea, vomiting, stomach irritation, abdominal pain, diarrhea, constipation, dry mouth.
Rare: inflammation/ulcers in the mouth (stomatitis/aphthous ulcers), sudden fluid accumulation in the intestines (intestinal angioedema), which can cause abdominal pain with or without nausea or vomiting.
Very rare: inflammation of the tongue (glossitis), stomach ulcer, inflammation of the pancreas accompanied by severe pain in the upper abdomen radiating to the back, nausea, and vomiting (pancreatitis).

**Liver and bile**Very rare: decreased liver function (liver insufficiency), bile flow obstruction (cholestasis, including jaundice (yellowing of the skin or eyes)), liver inflammation (hepatitis, with necrosis).

**Skin**Common: itching (pruritus), skin rash (rash sometimes accompanied by fever, arthralgia, and eosinophilia), hair loss (alopecia).

Sometimes: sudden fluid accumulation in the skin and mucous membranes (such as throat or tongue), difficulty breathing and/or itching or rash, often as an allergic reaction (angioedema).

Very rare: rash with intense itching and formation of bumps (urticaria) or maculopapular rash, severe hypersensitivity reaction with (high) fever, red spots on the skin, joint pain, and/or eye inflammation (Stevens-Johnson syndrome), rash with red (moist) irregular patches (erythema multiforme), photosensitivity, red, flaky skin (erythroderma), blistering (pemphigoid reactions), skin inflammation accompanied by peeling (exfoliative dermatitis).

**Bones and muscles**Very rare: muscle pain (myalgia), joint pain (arthralgia).

**Urinary tract and kidneys**Rare: decreased kidney function, increased urine output (polyuria), proteinuria, decreased urine production (oliguria), increased frequency of urination.
Very rare: nephrotic syndrome (kidney poisoning).

**Reproductive system and breasts**Very rare: impotence, abnormal development of male breasts, resembling female breasts (gynecomastia).

**General**Sometimes: chest pain, fatigue, malaise.
Very rare: fever.

**How to store this medicine?**

* Store below 25°C in the original packaging to protect from light and moisture.
* Keep out of sight and reach of children.
* Do not use this medicine after the expiry date stated on the packaging after "EXP". The expiry date is indicated as a month and a year. The last day of that month is the expiry date.
* Do not flush medicines down the sink or toilet or throw them in the trash. Ask your pharmacist how to dispose of medicines that you no longer use. They will be disposed of in a responsible manner and will not harm the environment.