

Captor 12.5mg, 25mg & 50mg Tablets

Captopril

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 Captor is and what it is used for
2. What you need to know before you take Captor
3. How to take Captor
4. Possible side effects
5. How to store Captor
6. Contents of the pack and other information

1 What Captor is and what it is used for

Captor is used to treat:

- **high blood pressure**
- **heart failure**
- **recovering heart attack patients**
- **kidney disease** resulting from diabetes

Captopril belongs to the ACE inhibitor medicine group (angiotensin-converting enzyme inhibitors). Captopril expands your blood vessels. This reduces your blood pressure and makes it easier for your heart to pump blood to all body parts.

2 What you need to know before you take Captor

Do not take Captor:

- if you are **allergic** to captopril or any of the other ingredients of this medicine (listed in section 6) or other ACE inhibitors
- if you or a family member had a reaction including **swelling of the face, lips, tongue** and/or **throat** with difficulty swallowing or breathing
 - to previous use of ACE inhibitors
 - without a known cause
- if you suffer from **narrowing of the aortic valve** (aortic stenosis) or other forms of a heart problem called outflow tract obstruction
- if you suffer from **narrowing of the arteries to your kidneys** (renal artery stenosis)
- if you are **more than 3 months pregnant**. (It is also better to avoid Captor 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
- If you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.

Warnings and precautions

Talk to your doctor or pharmacist before taking Captor if you:

- suffer from **dehydration** due to treatment with 'water tablets' (diuretics), dialysis, a low salt diet, vomiting or diarrhoea. After starting medication, a large drop in blood pressure may frequently occur and feeling faint or light-headed.
 - **suffer from heart disorders** such as heart failure, narrowing of the aortic or mitral valves (aortic or mitral stenosis) or an increase in the thickness of the heart muscle (hypertrophic cardiomyopathy or 'HOCM') or if you have a condition involving the blood vessels in the brain
 - have **kidney problems**
 - are undergoing **dialysis treatment**
 - with high flux membranes
 - blood separation treatment to remove cholesterol from your blood by machine with dextran sulphate
 - **desensitisation treatment** to reduce the effects of an allergy to a **bee or wasp sting**.
- In these cases tell your doctor that you are taking captopril. He/she may wish to interrupt your captopril treatment to prevent a possible allergic reaction.
- have **liver problems**. If you develop jaundice during use of captopril stop taking it and consult your doctor.
 - have **blood vessel disease**, known as collagen vascular disease
 - have a **cough** inform your doctor if this becomes worse.
 - are undergoing an **operation with a general anaesthetic**, inform your doctor about Captor
 - are taking **other medicines**, such as potassium supplements, lithium (for mental disorders) or medicines to manage diabetes
- If you are taking any of the following medicines, the risk of angioedema may be increased:
- Racecadotril, a medicine used to treat diarrhoea;
 - Medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus).
 - Vildagliptin, a medicine used to treat diabetes.
- are taking any of the following medicines used to treat high blood pressure:
 - an angiotensin II receptor blocker (ARBs) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems
 - aliskiren

In particular, talk to your doctor or pharmacist if you are taking, have recently taken or might take any of the following medicines:

- Potassium supplements (including salt substitutes), potassium-sparing diuretics and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole for infections caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots)

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 Captor”

- if you experience an **infection** with symptoms such as fever and serious deterioration of your general condition, or fever with local infection symptoms such as sore throat/pharynx/mouth or urinary problems, you should see your doctor immediately.

If you are unsure if any of the above apply to you, please discuss this with your doctor. Captor **may be less effective in black people**.

You must tell your doctor if you think you are (or might become) pregnant. Captor is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

Other medicines and Captor

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

This particularly applies to:

- **Medicines which are most often used to avoid rejection of transplanted organs(sirolimus, everolimus and other medicines belonging to the the classs of mTOR inhibitors). See section “Warnings and precautions”**
 - Potassium supplements or salt substitutes containing potassium, diuretics (water tablets, in particular those so-called potassium sparing), other drugs which can increase potassium in your body (such as heparin **and co-trimoxazole also known as trimethoprim/sulfamethoxazole**).
- **Diuretics** (‘water tablets’) which are used to treat high blood pressure including potassium-sparing diuretics such as spironolactone, triamterene or amiloride.
- Other **medicines** used to **treat high blood pressure**.
Your doctor may need to change your dose and/or to take other precautions. If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings ‘Do not take Captor’ and ‘Warnings and Precautions’)
- Medicines to treat arthritis or muscle pain, such as **ibuprofen** or **indomethacin**
- Medicines for mental disorders or depressions such as
 - **lithium**
 - **medicines to treat psychoses**
 - **tricyclic antidepressants**, such as amitriptyline

- **Potassium** containing supplements or salt substitutes
- **Blood sugar lowering medicines**, such as insulin or those taken orally. The antidiabetic medicine dose may need adjusting.
- Central nervous system stimulative medicines, such as
 - **ephedrine** or **pseudoephedrine**, which could be included in decongestants or cough/cold remedies or
 - **salbutamol**, a medicine for treating asthma
- **Medicines to suppress the body's immune system**
- **Allopurinol**, a medicine to treat gout
- **Procainamid**, used to treat abnormal heartbeats.

Pregnancy and breast-feeding

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Captor before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Captor. Captor is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breastfeeding or about to start breastfeeding. Breastfeeding newborn babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking Captor.

In the case of an older baby your doctor should advise you on the benefits and risks of taking Captor whilst breastfeeding, compared with other treatments.

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 any medicines.

Driving and using machines

Captor can affect your ability to drive, usually when you first start taking your medicine, if your doctor changes your dose or in combination with alcohol. If you feel light-headed or dizzy, you should not drive or operate machinery.

Captor contains lactose monohydrate.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to take Captor

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Take the tablets before, during or after meals with a glass of water.

The usual dose is:

- **For high blood pressure**

The usual starting dose is 12.5 – 25mg twice a day. Your doctor may gradually increase this dose to 100 – 150mg a day. You may also need to be given other medicines to lower your blood pressure.

- **Heart failure**

The usual starting dose is 6.25mg – 12.5mg two or three times a day. Your doctor may gradually increase this dose to a maximum of 150mg a day.

- **Following a heart attack**

The usual starting dose is 6.25mg, which will then be increased by your doctor to a maximum of 150mg a day.

- **Diabetic patients with kidney problems**

The usual dose is 75 – 100mg a day.

- **Patients with reduced kidney function**

If you suffer from a kidney disorder, the doctor may reduce your dose.

- **Elderly**

Older patients and those with kidney problems may be given a lower starting dose.

- **Children and adolescents**

The starting dose is 0.3mg/kg bodyweight, which may be increased gradually by the doctor. For children with kidney problems, premature babies and newborn babies and infants the starting dose should be 0.15mg/kg bodyweight.

If you take more Captor than you should

Contact your doctor or the nearest hospital casualty department immediately.

Take this leaflet or some tablets with you so that people will know what you have taken.

If you forget to take Captor

Take the missed dose as soon as you remember but never take two doses in one day.

If you stop taking Captor

Do not stop treatment before talking to your doctor, as this will reduce the treatment's effect.

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.

Allergic reaction signs and symptoms are:

- difficulties in breathing
- swelling of the face, hands, feet, lips, tongue and/or throat
- severe skin itch with raised lumps

Stop taking Captor and seek medical advice immediately, if you develop any of the allergic reaction signs.

Captor may cause a reduction in the number of white blood cells. Your resistance to infection may decrease and you may notice tiredness, an infection or a fever. If this happens contact your doctor.

Side effects can occur with the following frequencies:

Common: may affect up to 1 in 10 people

- sleep problems
- taste abnormalities
- dizziness
- dry, irritating cough
- shortness of breath
- feeling sick (nausea)
- vomiting
- stomach pain or discomfort
- abdominal pain
- diarrhoea
- constipation
- dry mouth
- itching with or without rash
- rash
- hair loss
- peptic ulcer
- indigestion

Uncommon: may affect up to 1 in 100 people

- increased heart rate
- angina
- heart palpitations
- irregular heart beat
- low blood pressure
- numbness or tingling in the fingers and toes
- flushing
- looking pale
- swelling of the eyes and lips (angioedema)
- chest pain
- tiredness
- general weakness
- decreased appetite
- headache

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

- sleepiness

- mouth ulcers
- swelling of the intestines which may cause stomach pain with or without nausea and vomiting
- kidney disorders or failure
- changes in frequency of passing urine
- excessive outputs of urine
- low output of urine

Very Rare: may affect up to 1 of 10,000 people

- deficiency of red blood cells with signs such as looking pale or feeling tired
- unexpected bruising
- blood abnormality and abnormalities of the lymph glands
- high levels of potassium in the blood
- low levels of sodium in the blood
- low blood sugar levels
- confusion
- depression
- cerebrovascular incidents, including stroke and lapse of consciousness
- blurred vision
- heart problems, including heart attack
- difficulty in breathing, stuffy nose, certain forms of pneumonia
- swollen tongue
- inflammation of the pancreas
- impaired liver function and raised liver enzymes
- liver damage, inflammation of the liver or jaundice (yellowing of the skin and/or the whites of the eyes)
- severe skin disorders including Stevens-Johnson Syndrome
- sensitivity of the skin to light
- muscle pain
- joint pain
- an abnormal condition of the kidney known as nephrotic syndrome
- inability to maintain an erection (impotence)
- enlargement of one or both breasts in men
- fever

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Captor

Do not store above 25°C. Store in the original package.

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 and carton after 'Exp'. The expiry date refers to the last day of that month.

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 Captor contains

- The active substance is captopril.
Each Captor 12.5mg tablet contains 12.5mg captopril.
Each Captor 25mg tablet contains 25mg captopril.
Each Captor 50mg tablet contains 50mg captopril.
- The other ingredients are microcrystalline cellulose, maize starch, lactose monohydrate and stearic acid.

What Captor looks like and contents of the pack

Captor 12.5mg is a white, round tablet with a score notch on one side. It is available in the following pack sizes: 20, 60 and 100 tablets.

Captor 25mg is a white, round tablet of a cloverleaf form with a facet and a crossed break mark on both sides. It is available in the following pack sizes: 20, 60 and 100 tablets.

Captor 50mg is a white, round tablet of a cloverleaf form with a facet and a crossed break mark on both sides. It is available in the following pack sizes: 60 and 100 tablets.

Please note that not all pack sizes will be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Rowex Ltd., Bantry, Co. Cork, Ireland

Manufacturers :

Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany

Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland

This leaflet was last revised in July 2017.