

Captopril 5mg/5ml Sugar Free Oral Solution

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.

The name of your medicine is Captopril 5mg/5ml Sugar Free Oral Solution but it will be referred to as 'Captopril' throughout this leaflet.

What is in this leaflet:

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

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1. What Captopril is and what it is used for

This medicine contains the active substance Captopril. Captopril belongs to the group of medicines called Angiotensin Converting Enzyme (ACE) Inhibitors. ACE inhibitors work by helping to widen your blood vessels, which then make it easier for your heart to pump blood through them.

Captopril is used to treat high blood pressure and certain heart conditions. If high blood pressure is left uncontrolled it can increase the risk of heart disease or stroke. Captopril works by lowering your blood pressure which reduces this risk.

Captopril can also help people whose heart no longer pumps blood as well as it once did. This condition is known as heart failure.

Captopril may also be used to treat patients who recently suffered a heart attack. A heart attack happens once one of the major blood vessels supplying blood to the heart muscle becomes blocked. This means that the heart does not receive the oxygen it needs and the heart muscle becomes damaged.

In addition, Captopril can be used for the treatment of kidney disease in patients with diabetes.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Captopril

Do not take Captopril if you:

- ▶ Are allergic to captopril or any of the other ingredients of this medicine (listed in section 6)
- ▶ Are more than 3 months pregnant (It is also better to avoid Captopril in early pregnancy – see pregnancy section)
- ▶ Have ever had an **allergic** reaction to any ingredients of Captopril or to any other medicines, including other ACE inhibitors
- ▶ Have ever had a **reaction** which included swelling of the hands, lips, face or tongue where the cause was unknown
- ▶ Suffer from any **auto-immune disease** (e.g. rheumatoid arthritis, systemic lupus erythematosus or sclerodema)
- ▶ Have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Captopril.

If you 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.

If you are taking any of the following medicines, the risk of angioedema (rapid swelling under the skin in area such as the throat) is increased:

- ▶ sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors (used to avoid rejection of transplanted organs)

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 Captopril if'.

You must tell your doctor if you:

- ▶ Think you are (or might become) pregnant. Captopril 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)
- ▶ Suffer from kidney disease
- ▶ Suffer from liver disease
- ▶ Are undergoing dialysis
- ▶ Suffer from heart disease, in particular problems with the valves of the heart
- ▶ Have diabetes
- ▶ Have recently suffered from excessive vomiting or diarrhoea
- ▶ Are receiving immuno-suppressant therapy.

If you are to have desensitisation treatment for wasp or bee stings you should tell the doctor who is treating you that you are taking Captopril.

If you are about to have treatment for the removal of cholesterol from your blood by a machine, (called LDL apheresis) you should tell your doctor you are taking Captopril.

Tell your doctor you are taking Captopril before you have any blood or urine tests as Captopril may interfere with the results of some tests.

Some Afro-Caribbean patients may require higher dose of Captopril to obtain an adequate reduction in blood pressure.

Children and adolescents

Safety and effectiveness in children have not been established. Newborns and infants may be at greater risk to the low blood pressure side-effects of Captopril.

Other medicines and Captopril

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription including herbal medicines. It is especially important to tell your doctor if you are taking any of the following:

- ▶ Non steroidal anti-inflammatory painkillers **NSAIDs** (e.g. indomethacin, ibuprofen)
- ▶ **Immunosuppressants** (e.g. azathioprine and cyclophosphamide)
- ▶ Potassium supplements or salt substitutes containing potassium, diuretics (**water tablets**, in particular those so called potassium sparing, e.g. amiloride, spironolactone), other drugs which can increase potassium in your body (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole)
- ▶ Medicines for **gout** (e.g. allopurinol)
- ▶ Medicines for **diabetes** (as the amount you need to use may have to be changed while taking Captopril)
- ▶ Medicines that cause dilation of the **blood vessels** (e.g. minoxidil, clonidine)
- ▶ Medicines to treat **mental health problems** including depression (such as lithium or amitriptyline)
- ▶ Any other medicines to treat **high blood pressure** (e.g. beta-blockers such as propranolol, atenolol or calcium channel blockers such as amlodipine, nifedipine)
- ▶ Any medicine that may be used during and after a **heart attack**
- ▶ Medicines which are most often used to avoid rejection of transplanted organs (sirolimus, everolimus and other medicines belonging to the class of mTOR inhibitors). See section "Warnings and precautions".

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 Captopril if' and 'Warnings and precautions').

Captopril with food, drink and alcohol

Captopril can be taken with or without food. Your doctor may advise you to limit the amount of salt in your diet while taking Captopril. Moderate amounts of alcohol will not affect Captopril, however, you should check with your doctor first to see if drinking is advisable for you.

Pregnancy and breast-feeding

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 this medicine.

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Captopril before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Captopril.

Captopril 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 after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Breast-feeding newborn babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking Captopril. In the case of an older baby your doctor should advise you on the benefits and risks of taking Captopril whilst breast-feeding, compared with other treatments.

If you are due to have surgery

Before surgery and anaesthesia (even at the dentist) you should tell your doctor or dentist that you are taking Captopril as there may be sudden fall in your blood pressure.

Driving and using machines

Captopril can affect your ability to drive, usually when you first start taking your medicine or if your doctor changes your dose. If you do feel light-headed or dizzy when taking Captopril, you should not drive or use machinery.

Captopril contains:

Sodium benzoate (E211): This medicine contains 1.25mg Sodium benzoate in each 5ml dose, which is equivalent to 0.25mg/ml. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old). Sodium: This medicine contains less than 1 mmol sodium (23 mg) per 5ml dose, that is to say essentially 'sodium-free'.

3. How to take Captopril

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

Note: Captopril Oral Solution is also available in 25mg/5ml strength which allows the dose to be taken in a smaller volume of solution. If you feel you would benefit from using the higher strength product, speak to your doctor.

The recommended doses are:

For the treatment of high blood pressure

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

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

In heart failure

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

After heart attack

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

For the treatment of diabetic patients with kidney disease

The usual dose is 75-100mg (75 - 100ml) a day.

For children

The starting dose is 0.3mg (0.3ml)/kg bodyweight, which may be increased gradually by the doctor.

For children with kidney problems, premature babies, new born babies and infants

The starting dose should be 0.15mg (0.15ml)/kg body weight.

Doctors sometimes prescribe different doses to the above and if this applies to you, you should discuss it with your doctor.

TURN OVER



Sometimes patients may feel dizzy after taking the first one or two doses of Captopril. If this happens to you, lie down until these symptoms disappear.

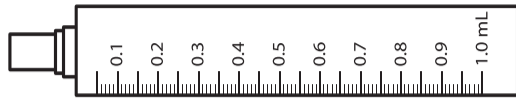
You should try to take Captopril at about the same time each morning. It can be taken before, during or after meals.

Even if you feel well continue to take Captopril until your doctor tells you otherwise.

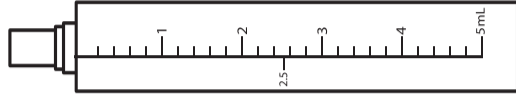
Route and method of administration

This medicine must be taken orally. Your doctor, pharmacist or nurse will show you how to administer this medicine by oral syringe or by a gastric feeding tube. The box containing this medicine will also contain a 1ml dosing syringe, a 5ml dosing syringe, and a syringe adaptor.

You may need to use both syringes in order to measure the correct dose.



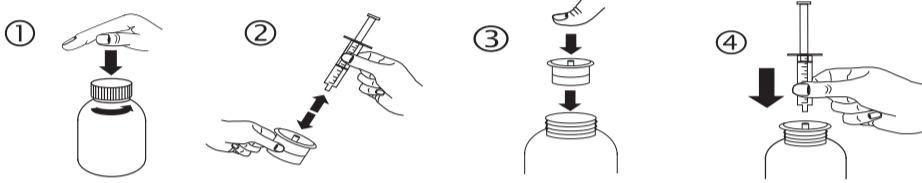
1ml syringe, each numbered increment is 0.1ml equivalent to 0.1mg Captopril Oral Solution.



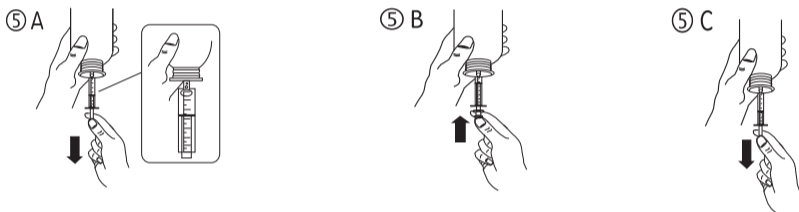
5ml syringe, each numbered increment is 1ml equivalent to 1mg Captopril Oral Solution. The smaller increments are 0.2ml (0.2mg) of the solution.

Instructions are provided below for using the dosing syringe. If you have any questions about the dose you should use or how to use the syringe, ask your pharmacist.

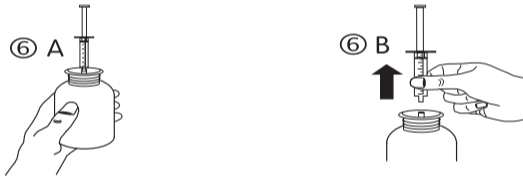
- Open the bottle: press the cap and turn it anticlockwise (figure 1).
- Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



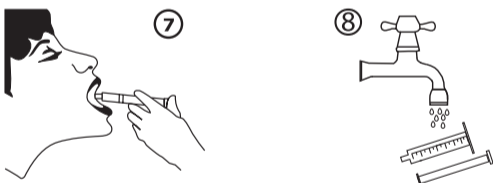
- Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).



- Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



- Empty the contents of the syringe into the patient's mouth by gently pushing the piston to the bottom of the syringe (figure 7). The contents of the syringe should be emptied into the side cheek of the patient's mouth to avoid a choking hazard. Close the bottle with the plastic screw cap. Do not remove the syringe adaptor from the bottle. Wash the syringe with water (figure 8).



If you take more Captopril than you should

If you or anyone else take more Captopril than you should go to your nearest hospital emergency department or tell your doctor immediately. Take the carton and any remaining Captopril you have with you. This will help the doctor identify what medicine you have taken.

If you forget to take Captopril

If you miss a dose do not worry. Just carry on taking your normal dose when the next one is due. **Do not** take a double dose to make up for a forgotten dose.

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.

If you experience any of the following reactions stop taking Captopril and contact your doctor **immediately**:

- Swelling of the hands, face, lips or tongue
- Difficulty in breathing
- A sudden, unexpected rash or burning, red or peeling skin
- Sore throat or fever
- Severe dizziness or fainting
- Severe stomach pain
- Unusually fast or irregular heartbeat
- Yellowing of the skin and/or eyes (jaundice).

Common side effects (may affect up to 1 in 10 people)

- Dizziness
- Itching
- Rashes
- Hair loss
- Changes in the way things taste
- Shortness of breath

- Dry mouth
- Sleep problems
- Diarrhoea or constipation
- Dry, irritating cough
- Upset stomach, feeling sick, vomiting, abdominal pain
- Stomach ulcers.

Uncommon side effects (may affect up to 1 in 100 people)

- Headache
- Fast, irregular, louder heartbeat
- Chest pain
- Low blood pressure
- Reduced blood flow to the hands and feet (e.g. Raynaud's phenomenon)
- Flushing
- Pins and needles, numbness or tingling
- Tiredness
- Generally feeling unwell
- Looking pale
- Swelling of the eyes and lips (angioedema)
- Loss of appetite.

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

- Drowsiness
- Mouth ulcers
- Kidney disorders or failure
- Changes in frequency of passing urine.

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

- Impaired liver function and raised liver enzymes
- Confusion, depression, fainting
- Mini stroke
- Blurred vision
- Heart problems including heart attack, and chest infections
- Inflammation of the pancreas
- Runny nose
- Swollen tongue
- Impotence
- Steven-Johnson syndrome (a serious illness with blistering of the skin, mouth, eyes and genitals)
- Liver damage, inflammation of the liver or jaundice
- Muscle pain
- Joint pain
- Wheezing or difficulty breathing
- Rashes or skin reactions
- Swelling of breast tissue in men
- Fever
- Sensitivity of the skin to light
- Changes in levels of cells and/or chemicals in the blood or lymphatic systems (e.g. red or white blood cells, sodium, potassium, sugars).

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist immediately. It will help if you make a note of what you experienced, when it started and how long it lasted.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Captopril

- 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 carton and label after 'EXP:'. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Discard 21 days after first opening.
- Do not use this medicine if you notice that the solution becomes discoloured or shows any signs of deterioration. Seek the advice of your pharmacist.
- Do not throw away any medicine 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 Captopril contains

The active substance is captopril.

Each 5ml of solution contains 5mg captopril.

The other ingredients are sodium benzoate (E211), citric acid monohydrate (E330), sodium citrate (E331), disodium edetate and purified water.

What Captopril looks like and contents of the pack

Captopril is a clear, colourless oral solution supplied in an amber glass bottle with tamper-evident child resistant plastic cap with a 1ml oral syringe with 0.01ml graduation marks and a 5ml oral syringe with 0.2ml graduation marks for measuring and administering the dose and a syringe adaptor.

Captopril Oral Solution is supplied in bottles containing 100ml oral solution.

Marketing Authorisation Holder:

SyriMed,
Unit 4, Bradfield Road,
Ruislip, Middlesex,
HA4 0NU, UK.

POM

Manufacturer:

Galenica Pharmaceutical Industry S.A.
Asklipiou 4-6, Kryoneri, Attiki,
14568, Greece

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Malta: Captopril Thame 5mg/5ml Sugar Free Oral Solution.

United Kingdom (Northern Ireland): Captopril 5mg/5ml Sugar Free Oral Solution.

If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.

This leaflet was last revised in 06/2023.



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