PACKAGE LEAFLET: INFORMATION FOR THE USER

Captopril 25mg/5ml Oral Solution

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, pharmacist or nurse.
- 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 or your child get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet (see section 4).

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What is in this leaflet

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

1. What Captopril Oral Solution is and what it is used for

Captopril Oral Solution contains the active substance captopril which 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 the following in adults, the elderly and children:
- 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.
- People whose heart no longer pumps blood as well as it once did. This condition is known as heart failure.
- People who have 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.
- Kidney disease in people with diabetes.

2 What you need to know before you take Captopril Oral Solution

Do not take Captopril Oral Solution if:
- you are allergic (hypersensitive) to captopril, any other ACE inhibitors, or any of the other ingredients of this medicine (listed in section 6).
- you have ever had a reaction which included swelling of the hands, lips, face or tongue where the cause was unknown.
- you are more than 3 months pregnant (it is better to avoid Captopril Oral Solution in early pregnancy; see pregnancy section).
- you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- 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.

If any of the above applies to you or your child you should ask your doctor's advice before taking this medicine.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Captopril oral solution.
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.

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 Oral Solution'.

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:
- 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.

You must tell your doctor if:
- you think you are (or might become) pregnant. Captopril Oral Solution is not recommended in 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)
- you are breast-feeding or about to start breast-feeding
- you are on a reduced-salt diet
- you are taking diuretic (water tablets)
- you have recently suffered from excessive vomiting or diarrhoea
- you are undergoing dialysis
- you have heart problems in particular problems with the valves of your heart
- you suffer from liver disease
- you have diabetes
- you get swelling in your face, neck or throat. This can occur at any time during treatment.
- you get any changes in the colour of your skin or the whites of your eyes, you must see your doctor immediately
- you are going to have an operation in hospital or you are going to the dentist
- you get stomach pains – you need to tell your doctor you are taking Captopril Oral Solution
- you feel ill, become aware of your heartbeat and get muscle weakness – you may have high amounts of potassium in your blood, your doctor will perform a blood test to check this.

Immunosuppressant therapy
If you are receiving immunosuppressant therapy your doctor may carry out a number of tests during your treatment with Captopril Oral Solution to make sure that you are showing no signs of an infection. If you begin to have symptoms of an infection such as a sore throat or fever you should contact your doctor **immediately**.

Patients with kidney disease
If you suffer from kidney disease your doctor may carry out a number of tests both before and during your treatment with Captopril Oral Solution to check the levels of protein in your urine.

Wasp sting desensitisation
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 Oral Solution. In rare cases a serious allergic reaction can happen if you have desensitisation treatment whilst taking this medicine.

Dialysis
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 Oral Solution. You may be given a different type of dialysis whilst taking this medicine.

Blood and urine tests
Tell your doctor or nurse you are taking Captopril Oral Solution before you have any blood or urine tests as this medicine may interfere with the results of some tests.

Ethnic differences
If you are Afro-Caribbean you may require higher doses of Captopril Oral Solution to reduce your blood pressure.

Taking other medicines and Captopril Oral Solution
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Captopril Oral Solution can affect the way some other medicines work.

In addition to this some other medicines can also affect the way Captopril Oral Solution works. It is especially important to tell your doctor if you are taking any of the following:
- Medicines used to treat asthma and colds (sympathomimetics) such as ephedrine and salbutamol
- Non steroidal anti-inflammatory (NSAIDs) painkillers, such as indomethacin and ibuprofen
- Medicines that make you pass more urine (diuretics) such as bendroflumethiazide and chlortalidone.
- Nitrates, medicines used to treat chest pain (angina) and heart problems such as glycerol trinitrate and isosorbide dinitrate
- Procainamide, a medicine used to treat an irregular heartbeat
- Aspirin (acetylsalicylic acid) and other medicines used to thin the blood
- Any other medicines to treat high blood pressure e.g. beta-blockers such as propanolol and atenolol, or calcium channel blockers such as amlodipine and nifedipine
- 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)
- Medicines used to treat diabetes (Insulins and sulphonylurea). Your dose may have to be adjusted while you are taking Captopril Oral Solution
- Lithium, a medicine used to treat a type of depression known as bipolar disorder
- Medicines used for cancer treatment or in patients who had a transplantation, (cytostatic agents/immunosuppressant agents), such as fluorouracil methotrexate, ciclosporin and azathioprine
- Medicines used to treat depression and other mental health problems such as amitriptylline and chlorpromazine. Taking these medicines with Captopril Oral Solution may make you feel dizzy or faint on standing up from a seated position.
- Allopurinol, a medicine used to treat gout

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 Oral Solution' and 'Warnings and precautions'.

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 Oral Solution as there may be a sudden fall in your blood pressure.

Pregnancy, breast-feeding and fertility

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 Oral Solution before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Captopril Oral Solution. Captopril Oral Solution 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 breast-feeding or about to start breast-feeding. Breast-feeding newborn babies (first few weeks after birth), especially premature babies, is not recommended whilst taking Captopril Oral Solution.
In the case of an older baby your doctor should advise you on the benefits and risks of taking Captopril Oral Solution whilst breast-feeding, compared with other treatments.

Driving or 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 Oral Solution, you should not drive or use machinery.

Captopril Oral Solution contains sodium and sodium benzoate
Captopril 25mg/5ml Oral Solution contains less than 1 mmol sodium (23 mg) per millilitre that is to say essentially 'sodium-free'.
Captopril 25mg/5ml Oral Solution contains 0.5mg sodium benzoate per millilitre. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Captopril Oral Solution odour
Do not be concerned if you smell a slight sulphurous odour (rotten egg) coming from Captopril Oral Solution. This does not mean that this medicine is unsuitable for use. Where possible we recommend to administer this medicine using the provided measuring syringe.

3. How to take Captopril Oral Solution

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

Switching between Captopril and other captopril formulations:

When you are taking Captopril Oral Solution, you should not change to using any different captopril containing medicines except under your doctor's supervision.

The 25mg/5ml product is supplied with the following administration devices:
- 5mL syringe graduated with numbered increments of 1mL (= 5mg captopril) and intermediate increments of 0.2mL (= 1mg captopril).
- 30 mL measuring cup graduated in numbered increments of 5 mL (= 25mg captopril) and intermediate increments of 1mL (= 5mg captopril).

Elderly patients or patients with kidney disorders:
Your doctor may start you on a lower dose. If you have a kidney disorder your doctor will increase the dose gradually until your blood pressure is adequately controlled up to a maximum of 150 mg per day.

The dosage may then be adjusted by your doctor to suit individual requirements.

For the treatment of high blood pressure:
The usual starting dose is 12.5 - 25 mg 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.

If you have kidney or heart problems or low levels of blood in your body you may be given a lower starting dose of 6.25mg or 12.5mg which may be

Continued overleaf

gradually increased to 50mg -100mg a day.

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

After a heart attack - short term treatment:
The usual starting dose is 6.25mg, which will then be gradually increased by your doctor to a maximum of 100mg a day.

After a heart attack - long term treatment:
The usual starting dose is 6.25mg, which will then be gradually increased by your doctor to a maximum of 150mg a day.

Use in diabetic patients:
The usual dose is 75 - 100mg a day. Elderly patients are usually started on a dose of 6.25mg twice daily.

Use in children:

Your doctor will prescribe the most appropriate strength of Captopril Oral Solution according to the child's age, weight and dose.

Make sure that the correct amount is measured out.

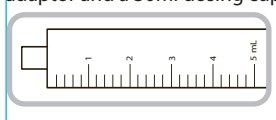
The starting dose is 0.3mg/kg body weight, divided into 3 equal doses daily. This may be increased gradually by the doctor.

For children with kidney problems, premature babies and newborn babies and infants
The starting dose should be 0.15mg/kg body weight. Make sure that the correct amount is measured out.

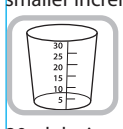
When to take Captopril Oral Solution
You should try to take Captopril Oral Solution at about the same time every day. As food does not affect how captopril is absorbed, it can be taken before, during or after meals.

SHAKE WELL BEFORE USE.

Method of administration:
Your doctor, pharmacist or nurse will show you how to administer this medicine. The box containing this medicine will contain a 5ml dosing syringe, a dosing adaptor and a 30ml dosing cup.



5ml syringe (purple barrel) each numbered increment is 1ml equivalent to 5mg of captopril. The smaller increments are 0.2ml or 1mg of captopril.

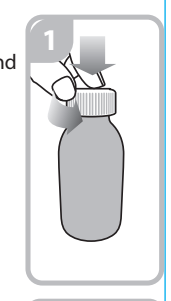


30ml dosing cup. Each numbered increment is 5ml - equivalent to 25mg of captopril. The intermediate increments are 1ml or 5mg of captopril.

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, you should ask your pharmacist.

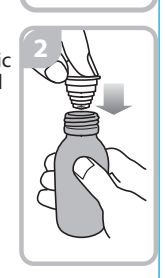
Instructions for use:

- Open the bottle: press the cap and turn it anticlockwise *(figure 1)*

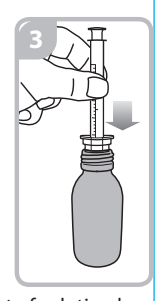


- Holding the bottle, take the plastic syringe adaptor from the box and insert the adaptor into the bottle neck *(figure 2)*.

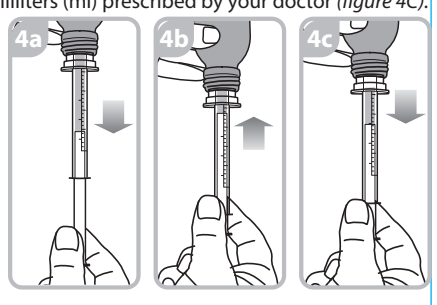
  Ensure it is well fixed.



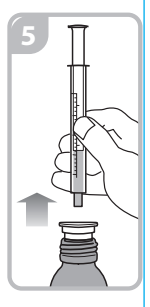
- Take the syringe and put it in the adaptor opening *(figure 3)*.
- Turn the bottle upside down.



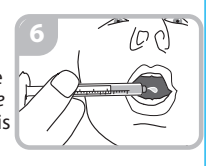
- Fill the syringe with a small amount of solution by pulling the piston down *(figure 4a)*, then push the piston upward in order to remove any possible bubble *(figure 4b)*. Pull the piston down to the graduation mark corresponding to the quantity in milliliters (ml) prescribed by your doctor *(figure 4C)*.



- Turn the bottle the right way up. Remove the syringe from the adaptor *(figure 5)*.



- Administer the contents of the syringe into the mouth by pushing the piston to the bottom of the syringe *(figure 6)* and ensure the medicine is swallowed.



  Remove the adaptor from the bottle and close the bottle with the plastic screw cap.

  Wash the adaptor, the syringe and the dosing cup where applicable with warm water after use. Dry them with a clean paper towel and replace them into the box with your medicine.

If you take more Captopril Oral Solution than you should
If you or any one else takes too much Captopril Oral Solution you should go to your nearest hospital emergency department or tell your doctor immediately. Take the carton and bottle with any remaining solution you have with you.

If you forget to take Captopril Oral Solution
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 the one you missed.

If you stop taking Captopril Oral Solution
You should not stop taking Captopril Oral Solution until your doctor tells you to, even if you feel well. If you feel you need to stop taking this medicine you should discuss this with your doctor before you stop taking it.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Serious side effects

If you (or your child) experience any of the following reactions stop taking Captopril Oral Solution and contact your doctor IMMEDIATELY:
- Swelling of the hands, face, lips or tongue
- Wheezing or difficulty in breathing
- Ulcers, blistering and skin rashes or burning, red, peeling skin on the lips, tongue and genitals, sometimes spreading to the eyes, face and body, (a very rare illness known as Stevens-Johnson syndrome)
- Sore throat or fever
- Severe dizziness or fainting
- Serious chest pains that travel down your left arm
- Fast, deep breathing, cold clammy skin and feelings of anxiety
- Severe stomach pain
- Yellowing of the skin and/or eyes

Other side effects

Common: May affect up to 1 in 10 people
- Fits are observed in infants
- Breathing problems in infant when asleep
- Changes in posture in infants
- Low urine amounts in premature infants
- Weight loss in premature infants
- Problems sleeping
- Changes in the way things taste
- Dizziness
- Dry, irritating cough
- Shortness of breath
- Feeling or being sick
- Indigestion or stomach pain
- Diarrhoea or constipation
- Dry mouth
- Itching or a red rash
- Hair loss

Uncommon: May affect up to 1 in 100 people
- A fast or irregular heartbeat, or feeling your heart beat (palpitations)
- Flushed or looking unusually pale
- Low blood pressure. You may feel dizzy or faint
- Painful, cold and discoloured fingers or toes caused by lack of blood to the area (Raynaud's syndrome)

Rare: May affect up to 1 in 1,000 people
- Loss of appetite
- Headache
- Tingling, prickling or numbness of the skin
- Drowsiness
- Pain and swelling inside the mouth
- Mouth ulcers
- Changes to your kidney function
  Your doctor will carry out tests to check this
- Changes in how often you pass urine
- Stomach cramps, abdominal pain, or pain that moves from the stomach around to your back
- Fatigue
- A general feeling of being unwell

Very Rare: May affect up to 1 in 10,000 people
- Bleeding gums or nosebleeds
- Swollen glands
- Changes in your blood. Your doctor will carry out tests to check this
- Changes in the amount of potassium, sodium and sugars in your blood. Your doctor will carry out tests to check this
- Confusion
- Depression
- Cerebrivascular incidents (e.g. stroke)
- Fainting
- Blurred vision
- Blocked or runny nose
- Chest tightness or a stabbing pain in your chest
- Changes to your liver function or liver damage.
  Your doctor will carry out tests to check this
- Itching and yellowing of the skin
- Sensitivity to light
- Muscle or joint pain
- Difficulty achieving or maintaining an erection
- Swelling of breast tissue in men (gynaecomastia)
- Fever
- Heart attack or heart shock
- Inflammation of the pancreas
- Stomach ulcers
- Stevens-Johnson syndrome(a serious illness with blistering of the skin, mouth, eyes and genitals)

Not known: Frequency cannot be estimated from the available data
- Disorder of the blood glucose regulating hormones with pronounced lowering of blood sugar levels (insulin autoimmune syndrome)

Reporting of side effects
If you or your child gets 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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Captopril Oral Solution

Keep this medicine out of the sight and reach of children.

Do not refrigerate. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C. Use within 21 days of opening.

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 to protect the environment.

6. Contents of the pack and other information

What Captopril Oral Solution contains
The active substance is captopril 25mg/5ml.
The other ingredients are disodium EDTA, sodium benzoate (E211), citric acid (E330), sodium citrate (E331) and purified water. May also contain sodium hydroxide (E524) for pH adjustment.

What Captopril Oral Solution looks like and the contents of the pack
Captopril 25mg/5ml Oral Solution is a clear, colourless solution supplied in 100ml amber glass bottles. Each pack contains one bottle of solution, a 5ml dosing syringe, a syringe adaptor to fit onto the bottle when measuring the dose and a 30ml dosing cup.

Marketing Authorisation Holder and Manufacturer:
Martindale Pharamaceuticals Limited,
Bampton Road,
Harold Hill,
Romford,
Essex,
RM3 8UG,
United Kingdom

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Product licence number:
PL 00156/0362

MARTINDALE PHARMA
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100mm Measurement Verification Bar