XLS04

Information for the user

Captopril 5 mg/5 ml Oral Solution
Captopril 25 mg/5 ml 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 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 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 of this leaflet)
- you or any members of your family 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 suffer from narrowing of the aortic valve (aortic stenosis) or other forms of a heart problem called outflow tract obstruction
- you suffer from narrowing of the arteries to your kidneys (renal artery stenosis)
- 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'

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

- Medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus)
- Racecadotril, a medicine used to treat diarrhoea
- 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 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)

- 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
- 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, tell your doctor. 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, tell your doctor. 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

Tell your doctor if you are undergoing dialysis. Captopril is not adequately cleared by peritoneal dialysis.

Apheresis

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 to reduce your blood pressure.

Children and adolescents

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

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 glyceryl 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 propranolol and atenolol, or calcium channel blockers such as amlodipine and nifedipine
- Potassium supplements (including salt substitutes), potassium-sparing diuretics and other medicines which can increase potassium in your body, such as amiloride and spironolactone and others (e.g. trimethoprim and co-rimoxazole 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 amitriptyline 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
- 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 headings 'Do not take Captopril Oral Solution if' 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 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 Oral Solution, you should not drive or use machinery.

Captopril Oral Solution contains Sodium

Captopril 5 mg/5 ml Oral Solution contains 4.4 mg sodium (main component of cooking/table salt) in each 5 ml.

This is equivalent to 0.22% of the recommended maximum daily dietary intake of sodium for an adult.

Captopril 25 mg/5 ml Oral Solution contains 4.4 mg sodium (main component of cooking/table salt) in each 5 ml. This is equivalent to 0.22% of the recommended maximum daily dietary intake of sodium for an adult.

(continued overleaf)

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.

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

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 - 150 mg 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 6.25 mg or 12.5 mg which may be gradually increased to 50 mg - 100 mg a day.

For treatment in heart failure:

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

After a heart attack - short term treatment:

The usual starting dose is 6.25 mg, which will then be gradually increased by your doctor to a maximum of 100 mg a day.

After a heart attack - long term treatment:

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

Use in diabetic patients:

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

Use in children and adolescents:

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.

For children, the starting dose is 0.3 mg/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 0.15 mg/kg body weight. Make sure that the correct amount is measured out.

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

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.

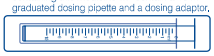
When to take Captopril Oral Solution

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 10 ml graduated dosing pipette and a dosing adaptor.



10 ml pipette, each numbered section is 1 ml and the smaller increments are 0.25 ml.

Captopril 5 mg/5 ml Oral Solution: 1 ml is equivalent to 1 mg and 0.25 ml is equivalent to 0.25 mg

Captopril 25 mg/5 ml Oral Solution: 1 ml is equivalent to 5 mg and 0.25 ml is equivalent to 1.25 mg

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

Instructions for use:

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

- On using the bottle for the first time, the pipette adaptor must be fitted. It will then stay in place for future doses. Holding the bottle, take the plastic pipette adaptor from the box and insert the adaptor into the bottle neck (figure 2). Ensure it is well fixed.

- Take the pipette and put it in the adaptor opening (figure 3).
- Hold the pipette in place and turn the bottle upside down.

- Still holding the pipette in place, pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 4).

- Turn the bottle the right way up. Remove the pipette from the adaptor (figure 5).
- Administer the contents of the pipette into the mouth by pushing the piston to the bottom of the pipette and ensure the medicine is swallowed.

Do not remove the adaptor from the bottle neck, it is intended to stay in place. Close the bottle with the plastic screw cap.

Wash the pipette with warm water. Dry it with a clean paper towel and replace into the box with your medicine.

If you take more Captopril Oral Solution than you should

If you, or anyone else, take 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:

- Unusually fast or irregular heartbeat
- Severe dizziness or fainting
- Severe stomach pain
- Sore throat or fever
- Swelling of the hands, face, eyes, lips or tongue (angioedema)
- Wheezing or difficulty in breathing
- Ulcers, blistering and sudden, unexpected 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)
- Serious chest pains that travel down your left arm
- Fast, deep breathing, cold clammy skin and feelings of anxiety
- Yellowing of the skin and/or eyes (jaundice)

Other side effects

Common: May affect up to 1 in 10 people

- Fits are observed in infants
- Breathing problems in infants 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
- Stomach ulcers
- Diarrhoea or constipation
- Dry mouth
- Itching or a red rash
- Hair loss

Uncommon: May affect up to 1 in 100 people

- Headache
- Feeling your heart beat (palpitations)
- Chest pain
- 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)
- Tingling, prickling or numbness of the skin
- Fatigue
- A general feeling of being unwell
- Loss of appetite

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

- Drowsiness
- Pain and swelling inside the mouth
- Mouth ulcers
- Changes to your kidney function (kidney disorders or failure)

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

Very Rare: May affect up to 1 in 10,000 people

- Bleeding gums or nosebleeds
- Swollen glands
- Changes in levels of cells and/or chemicals in the blood or lymphatic systems (e.g. red or white blood cells, potassium, sodium and sugars).

Your doctor will carry out tests to check this

- Confusion
- Depression
- Mini-stroke
- Blurred vision
- Blocked or runny nose
- Chest tightness or a stabbing pain in your chest, chest infections
- Changes to your liver function or liver damage. Your doctor will carry out tests to check this
- Itching and yellowing of the skin
- Sensitivity of the skin to light
- Muscle or joint pain
- Difficulty achieving or maintaining an erection
- Swelling of breast tissue in men (gynaecomastia)
- Heart problems including heart attack or heart shock
- Inflammation of the pancreas

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 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 Oral Solution

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 bottle label after EXP.

The expiry date refers to the last day of that month.

Do not store above 25°C. Do not freeze. Use within 28 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
- **Captopril 5 mg/5 ml Oral Solution** contains 5 mg of captopril per 1 ml
- **Captopril 25 mg/5 ml Oral Solution** contains 25 mg of captopril per 1 ml
- The other ingredients are citric acid monohydrate (E330), sodium citrate dihydrate (E331), sodium benzoate (E211), disodium edetate (E386), purified water.

What Captopril Oral Solution looks like and contents of the pack

Captopril Oral Solution is a clear, colourless solution supplied in 100 ml amber glass bottles closed with tamper-evident child-resistant plastic caps. Each pack contains one bottle of solution, a 10 ml dosing pipette and a bottle adaptor.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:

Ten Pharma
1 Thane Road West,
Nottingham,
England, NG2 3AA
United Kingdom

Manufacturer:

BCM Limited
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