Captopril 25mg/5ml Sugar Free Oral Solution

Package leaflet: Information for the user

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 25mg/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

1. What Captopril is and what it is used for

The name of this medicine is 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.

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).
► You are more than 3 months pregnant (It is also better to avoid Captopril in early pregnancy – see pregnancy section).
► You have ever had an allergic reaction to any ingredients of Captopril or to any other medicines, including other ACE inhibitors.
► You have ever had a reaction which included swelling of the hands, lips, face or tongue where the cause was unknown.
► You suffer from any auto-immune disease (e.g. rheumatoid arthritis, systemic lupus erythematosus or scleroderma).
► You 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.

3. How to take Captopril

The usual starting dose is 6.25mg (1.25ml) two or three times a day. Your doctor may advise you to gradually increase this dose to a maximum of 150mg (30ml) a day.

4. Possible side effects

The side effects of Captopril, may include:
► Dizziness
► Headache
► Fatigue
► Dry mouth
► Abdominal discomfort
► Menstrual disorders
► Gastrointestinal disorders
► Anorexia
► Cough
► Rash
► Elevated liver enzymes
► Impotence
► Changes in taste
► Changes in blood pressure

5. How to store Captopril

Store below 25°C

6. Contents of the pack and other information

Captopril 25mg/5ml Sugar Free Oral Solution contains:
► 25mg captopril (as captopril acid)
► 5ml sugar free oral solution

First aid

If you take too much Captopril (overdose)

Details of over dosage (acute poisoning) may be found in the summary of product characteristics.

This medicinal product also contains 0.088mmol (or 2.02mg) sodium per 5 ml of solution. To be taken into consideration by patients on a controlled sodium diet.

Driving and using machines

Driving and using machines is not generally affected by Captopril. In patients who have heart failure, some people have been known to experience dizziness or faintness.

Breast-feeding

Captopril is not recommended whilst breast-feeding, compared with other treatments.

Pregnancy and breast-feeding

Captopril can cause harm to the baby. Your doctor may advise you to limit the amount of salt in your diet while taking Captopril.

Pregnant women

Captopril is not recommended whilst breast-feeding, compared with other treatments.

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 while breast-feeding, compared with other treatments.

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 5mg/5ml strength which allows small doses to be measured more accurately. If you feel you would benefit from using the lower strength product speak to your doctor and before The recommended doses are:

For the treatment of high blood pressure

The usual starting dose is 12.5 - 25mg (2.5-5ml) twice a day. Your doctor may gradually increase this dose to 100 - 150mg (20-30ml) a day. You may also need to take 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 (1.25-2.5ml) two or three times a day. Your doctor may gradually increase this dose to a maximum of 150mg (30ml) a day.

After heart attack

The usual starting dose is 6.25mg (1.25ml), which will then be increased by your doctor to a maximum of 150mg (30ml) a day.

For the treatment of diabetic patients with kidney disease

The usual starting dose is 75-100mg (15 – 20ml) a day.

For children

The starting dose is 0.3mg (0.06ml/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 (0.03ml/kg body weight).

Doctors sometimes prescribe different doses to the above and if this applies to you, you should discuss it with your doctor.
Swelling of the hands, face, lips or tongue
Upset stomach, feeling sick, vomiting, abdominal pain
Rashes
Severe dizziness or fainting
Heart problems including heart attack, and chest infections
Changes in frequency of passing urine.
Pins and needles, numbness or tingling
Runny nose
Blurred vision
Liver damage, inflammation of the liver or jaundice
Swelling of the eyes and lips (angioedema)
Mini stroke
Mouth ulcers
Looking pale
Yellowing of the skin and/or eyes (jaundice).
Headache
Dizziness
Hair loss
Do not throw away any medicine via waste water or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

Impaired liver function and raised liver enzymes
Dry, irritating cough
Sensitivity of the skin to light
Joint pain
Do not store above 30°C.
Impotence
Difficulty in breathing
Drowsiness
Chest pain
Confusion, depression, fainting
Reduced blood flow to the hands and feet (e.g. Raynaud’s phenomenon)
Muscle pain
Diarrhoea or constipation
Kidney disorders or failure
Swollen tongue
Generally feeling unwell
Fast, irregular, louder heartbeat
Stomach ulcers.

Common side effects (affecting between 1 in 10 and 1 in 100 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 (affecting between 1 in 100 and 1 in 1000 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 (affecting between 1 in 1000 and 1 in 10,000 people)
Drowsiness
Mouth ulcers
Kidney disorders or failure
Changes in frequency of passing urine.

Very rare side effects (affecting less than 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 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
Keep this medicine out of the sight and reach of children.
Do not use after the expiry date which is stated on the carton or bottle 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 waste water or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information
What Captopril contains
The active substance is captopril.
Each 5ml of solution contains 25mg 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 5ml oral syringe with 0.2ml, 2.5ml, 7.5ml graduation marks and 30ml measuring cup with 5ml graduation marks and having additional graduation of 2.5ml (12.5mg) and 7.5ml (37.5mg).

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

Marketing Authorisation Holder and Manufacturer:
Thame Laboratories, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK

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