Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

1. WHAT CAPTOPRIL TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Captopril 12.5mg, 25mg or 50mg Tablets. They contain the active ingredient called captopril. Captopril belongs to a group of medicines called ACE inhibitors. It works by lowering your blood pressure to normal levels if it is too high. It also acts to help your heart or kidneys to work better. Captopril Tablets may be used for:

- high blood pressure
- congestive heart failure (condition in which the heart cannot pump enough blood to the body’s other organs)
- diabetic nephropathy (kidney disease that occurs as a result of diabetes)

2. BEFORE YOU TAKE CAPTOPRIL TABLETS

Do not take Captopril Tablets if you are allergic (hypersensitive) to captopril or any of the other ingredients of Captopril Tablets. See section 6.

Take special care with Captopril Tablets if you:

- have liver or kidney problems
- have a condition called aortic stenosis (narrowing of the aortic valve in the heart)
- have a condition called collagen vascular disease. Collagen is a tough, glue-like protein that represents 30% of body protein and shapes the structure of tendons, bones, and connective tissues. Malfunctioning of the immune system can affect these structures. This is known as collagen vascular disease.
- are a patient undergoing immunosuppressant therapy (therapy designed to produce immunity to a disease or to enhance resistance of the immune system).
- have angioedema (a spontaneous swelling up of areas of skin)

Other precautions you should take:

If you see another doctor, attend hospital or the dentist for surgery involving an anesthetic, let them know what medicines you are taking.

Taking Captopril Tablets with food and drink

- Talk to your doctor before using salt substitutes containing potassium. If your doctor prescribes a low-salt or low-sodium diet, follow these instructions carefully.
- Alcohol may enhance the blood pressure lowering effect of this medicine, which may result in dizziness or fainting.
- You should drink plenty of water while taking captopril, particularly when exercising or in hot weather. If you sweat a lot or are not drinking enough water while taking captopril, you may feel light-headed or faint. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

Taking other medicines

You should tell your doctor if you are taking or have taken any of the following medicines as they may interact with your Captopril Tablets. Examples of medicines that can affect Captopril Tablets are:

- clonidine, which is used to treat high blood pressure
- procainamide, which is used to treat serious irregular heartbeat
- non-steroidal anti-inflammatory drugs (NSAIDs), such as Indometacin used to treat inflammation, mild to moderate pain, and fever.
- vasodilators (medicines that relax smooth muscle in blood vessels, causing them to dilate) such as Minoxidil
- diuretics (“water tablets”) used to treat oedema, an intense accumulation of fluids in the body’s tissues or high blood pressure.
- allopurinol or probenecid which are used in the treatment of gout, immunosuppressants such as azathioprine & cyclophosphamide, which are used to dampen down the activity of the body’s immune system.
- lithium, which is used to treat some types of depression
- medicines used to lower blood glucose level in diabetes such as ACE inhibitors.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

3. HOW TO TAKE CAPTOPRIL TABLETS

Always take Captopril Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

DOSEAGE - Follow the doctor’s advice on how and when to take the tablets. You should swallow the tablets whole with a glass of water. Take captopril at the same time each day to ensure a routine is kept.
The dose may vary from patient to patient as it is dependent upon your condition and how you react to this medicine. Follow all directions given to you by your doctor and pharmacist carefully.

**Adults:**
- **High blood pressure**
  Treatment with Captopril Tablets may be started with lowest effective dose. Your doctor will decide which dose is right for you.
- **Mild to Moderate high blood pressure**
  The usual starting dose is 12.5mg tablets two times each day. The usual maintenance dose is 25mg two times each day which can be increased gradually at 2-4 weeks interval, until a satisfactory response is received to a maximum of 50mg two times each day. Your doctor may also give this medicine in combination with thiazide diuretic (water tablets) if satisfactory response has not been received. The dose of diuretic may be increased at 1-2 week interval to the level of optimum response or until the maximum dose is reached.
- **Severe high blood pressure**
  The usual starting is 12.5mg tablets two times each day. This dose may be gradually increased to a maximum of 50mg three times each day. A daily dose of 150mg of Captopril should not normally be increased. Your doctor will decide which dose is right for you.
- **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 each day.
- **Myocardial Infarction**
  The usual dose is 6.25mg which will then be increased by your doctor to a maximum of 150mg each day in divided doses over the next several weeks.
- **Diabetic Nephropathy** (diabetic patients with kidney disease)
  The usual dose for diabetic patients with kidney disease is 75mg to 100mg each day in divided doses.
- **Elderly**
  If you are elderly, the dose you take will be similar to the adults. Your doctor may prescribe you with the lowest effective doses.

**Children:**
This medicinal product is not recommended for treatment of mild to moderate high blood pressure in children.

For children with kidney problems, premature babies and newborn babies and infants, the starting dose should be the lowest effective dose. The usual starting dose is 0.3mg/kg bodyweight which may be increased gradually by the doctor up to a maximum of 6mg/kg bodyweight each day in divided doses.

**Patients with kidney disease**
You will usually be given a lower dose depending on how severe your kidney damage is. The usual dose is 75 to 100mg each day.

If you take more Captopril Tablets than you should:
- If you take more Captopril Tablets than you should, contact your doctor or nearest hospital emergency department immediately. Take the pack and remaining tablets with you.

If you forget to take Captopril Tablets:
If you forget to take a dose, take it as soon as you remember unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Captopril:
Do not stop taking Captopril Tablets without talking to your doctor, even if you feel better. Continue with Captopril Tablets until your doctor tells you otherwise. Keep your doctor’s appointments even if you feel well.

4. **POSSIBLE SIDE EFFECTS**

Like all medicines, Captopril Tablets can cause side effects, although not everybody gets them.

**Very serious side effects** – If any of the following happens, stop taking Captopril Tablets and tell your doctor immediately or go to the nearest hospital emergency department:

- **Rare allergic (hypersensitive) reactions such as difficulty of breathing, swelling of your face, throat or tongue, skin rash, itching or nettle rash.**
- **Other possible side effects:**
  - dizziness, lightheadedness, faintness
  - swelling of the hand, feet, or mucous membranes (thin skin lining all animal body cavities and canals that come into contact with the air (for example, eyelids, breathing and digestive passages, genital tract))
  - decrease in the number of platelets in the blood (thrombocytopenia)
  - decrease in the number of a type of white blood cell (neutrophil) in the blood (neutropenia)
  - increase in red blood cells (anemia)
  - increase in total amount of protein in the blood
  - excessive blood acidity (acidosis)
  - faster than normal heart beat
  - drop in blood pressure
  - cough or difficulty in breathing (bronchospasm)
  - swelling of the lymph nodes
  - burning, pricking, itching, or tingling of hands
  - skin rash which can be itchy, blood spots, bruising and discolouring to the skin
  - excess of serum proteins in the urine
  - weight loss
  - loss of taste
  - inflammation of the mouth
  - liver problems
  - kidney problems
  - dry cough
  - angioedema (a spontaneous swelling up of areas of skin)
  - Jaundice (yellow skin/eyes)
  - sensitivity to light
  - tingling or numbness in the hands or feet
  - upset stomach, sickness, abdominal pain
  - inflammation of the pancreas

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. **HOW TO STORE CAPTOPRIL TABLETS**

Keep out of the reach and sight of children. Do not store the tablets above 30°C. Store in a cool dry place. Protect from light. Keep them in the original pack. Do not take these tablets after the expiry date shown on the pack. The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. **FURTHER INFORMATION**

What Captopril Tablets contain
The active ingredient in your tablets is captopril. Each Captopril 12.5mg Tablet contains 12.5mg of the active ingredient Captopril.
Each Captopril 25mg Tablet contains 25mg of the active ingredient Captopril.
Each Captopril 50mg Tablet contains 50mg of the active ingredient Captopril.
The other ingredients are lactose monohydrate, maize starch, microcrystalline cellulose, stearic acid.

Packaging:
Captopril 12.5mg Tablets - They are available in packs of 30, 45, 50, 56, 90 & 100 tablets.
Captopril 25mg Tablets - They are available in packs of 30, 45, 50, 56, 90 & 100 tablets.
Captopril 50mg Tablets - They are available in packs of 30, 45, 50, 56, 90 & 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
Fourrts (UK) Pharmacare Ltd, 30 Chaul End Lane, Luton, Bedfordshire, LU4 8EZ, U.K.
Tel: 01582 560393 Fax: 01582 569009 e-mail: ra@fourrts.com
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Not all pack sizes may be marketed.
- They are available in packs of 30, 45, 50, 56, 90 & 100 tablets.
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