

FLAT DIMENSION = 180 x 560mm  
FOLDED DIMENSION = 180 x 35mm

30 mm

10 mm

#### Package leaflet: Information for the user

### CAPTOPRIL 12.5 MG, 25 MG & 50 MG TABLETS 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, please 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 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 Tablets are and what they are used for
2. What you need to know before you take Captopril Tablets
3. How to take Captopril Tablets
4. Possible side effects
5. How to store Captopril Tablets
6. Contents of the pack and other information

### 1. What Captopril Tablets are and what they are used for

The name of this medicine is Captopril Tablets. The active ingredient is Captopril.

Captopril belongs to a 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 (hypertension), congestive heart failure, kidney problems caused by diabetes, and to improve survival after a heart attack.

### 2. What you need to know before you take Captopril Tablets

#### Do not take these tablets if you:

- are allergic to captopril, any of the other ingredients in these tablets or other ACE inhibitors (listed in section 6)
- have ever had a **reaction** which included swelling of the hands, lips, face or tongue where the cause was unknown
- are more than 3 months pregnant or breast-feeding (it is also better to avoid Captopril in early pregnancy - see pregnancy section.)
- have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren

- 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.
- are taking any of the following medicines, the risk of angioedema may be 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.

Do not take Captopril tablets if any of the above apply to you. If you are not sure, talk to your doctor before taking Captopril tablets.

#### Warnings and precautions

**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).**

Talk to your doctor, pharmacist or nurse if you:

- suffer from liver or kidney disease
- are undergoing dialysis
- suffer from heart disease, in particular problems with the valves of the heart
- are taking diuretic (water tablets)
- get swelling in your face, neck or throat. This can occur at any time during treatment.
- get any changes in the colour of your skin or the whites of your eyes, you must see your doctor immediately
- get stomach pains – you need to tell your doctor you are taking Captopril
- 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.
- are on a reduced-salt diet
- have diabetes
- if you suffer from any collagen vascular disease (e.g. rheumatoid arthritis, systemic lupus erythematosus or scleroderma).
- If you experience more infections such as sore throat or fever which can be due to changes in your blood cells and can be monitored by a blood test carried out by your doctor.
- If you are going to have dental surgery or major surgery involving anaesthetic.
- 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)
- have recently suffered from excessive vomiting or diarrhoea
- are receiving immuno-suppressant therapy

- 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 these tablets if you”

- are to have desensitisation treatment, e.g. for an allergic reaction to wasp or bee stings
- are about to have treatment for the removal of cholesterol from your blood by a machine, (called LDL apheresis)

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

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

#### Other medicines and Captopril

**Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.**

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 these tablets if you” and “Warnings and Precautions”).

It is especially important to tell your doctor if you are taking any of the following:

- Potassium supplements or salt substitutes containing potassium, diuretics (water tablets, in particular those so called potassium sparing e.g. triamterene, amiloride and spironolactone), other drugs which can increase potassium in your body (such as heparin and co-trimoxazole also known as trimethoprim/sulfamethoxazole).
- Medicines that cause dilation of the blood vessels (e.g. minoxidil, and clonidine)
- Medicines to treat mental problems including manic depression or depression (e.g. lithium and amitriptyline)
- Immuno-suppressants (e.g. azathioprine and cyclophosphamide)
- Medicines to treat gout (e.g. allopurinol and probenecid)
- Medicines to treat irregular heartbeats (e.g. procainamide)

- Non-steroidal anti-inflammatory painkiller (NSAIDS) (e.g. indometacin and ibuprofen)
- Medicines to treat diabetes (e.g. oral antidiabetics and insulin). The amount you need to use may have to be changed while taking Captopril
- Medicines to treat high blood pressure (e.g. beta-blockers such as propranolol, atenolol or calcium channel blockers such as amlodipine and 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”.

#### Captopril with food, drink and alcohol

Captopril can be taken with or without food.

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, breast-feeding and fertility

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 when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

#### Breastfeeding

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 a 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 tablets, you should not drive or use machinery.

#### Captopril Tablets contain Lactose

If you have been told by your doctor that you have intolerance to some sugars (such as lactose), contact your doctor before taking this medicinal product.

### 3. How to take Captopril Tablets

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

- The tablets should be swallowed whole with a glass of water.

The recommended doses are as follows:

#### For the treatment of high blood pressure (hypertension)

- The recommended starting dose is 12.5 - 25mg 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.

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

#### In heart failure

- The recommended 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

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

#### For the treatment of diabetic patients with kidney disease

- The recommended dose is 75 - 100mg a day.

#### Elderly patients (over 65 years)

Your doctor may start you on lower dose. If you have a kidney disorder your doctor will increase the dose gradually until your blood pressure is adequately controlled. The dosage may then be adjusted by your doctor to suit individual requirements.

#### For children

If this medicine is prescribed for a child make sure that the tablets are taken as stated on the label. The dosage for children is worked out on the basis of child's weight in kilograms.

The recommended starting dose is 0.3mg/kg body weight daily. If required, your doctor may increase the dose gradually.

Same Size Artwork  
Size: 560 x 180 mm  
Front

560 mm

10 mm

180 mm

#### For children with kidney problems, premature babies and newborn babies and infants

- The starting dose should be 0.15mg/kg bodyweight.

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.

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.

#### If you take more Captopril tablets than you should

If you or someone else swallow several of these tablets together, contact your doctor or nearest hospital emergency department immediately. Always take any tablets left over with you, this leaflet and also the box, as this will allow easier identification of the tablets.

#### If you forget to take Captopril tablets

If you miss a dose, take it as soon as you remember and carry on as before. If it is almost time for your next dose, skip the forgotten dose and continue as usual. Do not take a double dose to make up for a forgotten dose.

#### If you stop taking these tablets

Do not stop taking these tablets without first talking to your doctor.

If you have any further questions on the use of this product, 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, eyes, 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

- Severe stomach pain,
- Unusually fast, or irregular, heartbeat
- Liver damage, inflammation of the liver or jaundice
- Chest pain or discomfort

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

- Dry mouth
- Itching or a red rash
- Sleep problems
- Rashes
- Diarrhoea or constipation
- Hair loss
- Dry, irritating cough
- Upset stomach, sickness, abdominal pain, vomiting
- Shortness of breath
- Loss of taste (usually reversible on stopping treatment)
- Dizziness
- Changes in the way things taste
- Stomach ulcers

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

- Tiredness, generally feeling unwell
- Chest pain
- Low blood pressure
- Flushed or looking unusually pale
- Reduced blood flow to the hands and feet (e.g. Raynaud syndrome)
- Headache
- Fast, irregular, louder heartbeat
- Lack of energy and strength
- Pins and needles, numbness or tingling
- Decreased appetite
- Swelling of the eyes and lips (angioedema)

#### Rare side effects (may affect up to 1 in 1000 people)

- Loss of appetite and weight loss
- Mouth ulcers
- Drowsiness
- Kidney disorders or failure
- Changes in frequency of passing urine
- Allergic reaction in the gut causing severe abdominal pain (intestinal angioedema)

#### 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, stroke
- Muscle or joint pain
- Blurred vision
- Heart problems including heart attack, and chest infections
- Inflammation of the pancreas
- Runny nose
- Swelling of breast tissue in men, impotence
- Swollen tongue
- Sensitivity of the skin to light
- Fever
- Multiple damages to the kidneys
- Inflammation of lymph nodes
- Changes in levels of cells and/or chemicals in the blood or lymphatic systems (e.g. red or white blood cells, sodium, potassium, sugars)
- Changes in your blood and your blood cells.
- Liver damage, inflammation of the liver or jaundice 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).

Your doctor will carry out tests to check this.

- Rashes or skin reactions
- Psoriasis and psoriasisiform dermatitis

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](http://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 Tablets

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after expiry date (EXP) which is stated on the carton. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store in the original package.
- Do not throw away any medicines via waste water 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 Tablets contain

- The active substance is Captopril.
- The other ingredients are: Lactose monohydrate, Maize starch, Microcrystalline cellulose and Stearic acid.

##### What Captopril Tablet looks like and contents of the pack

- Captopril 12.5mg tablets: White to almost white, round, biconvex, uncoated tablets with "12.5" debossed on one side.
- Captopril 25mg and 50mg tablets: White to almost white, round, flat, bevelled edged, uncoated tablets with score line on one side and "25" or "50" debossed on the other side.
- Captopril tablets are available in packs of 28 and 56 tablets. Not all pack sizes may be marketed.

##### Marketing Authorisation Holder and Manufacturer

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**Captopril 12.5mg tablets; PL 17907/0037**

**Captopril 25mg tablets; PL 17907/0038**

**Captopril 50mg tablets; PL 17907/0039**

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To request a copy of this leaflet in a braille, large print or audio format, please contact the marketing authorisation holder at the address above (telephone or email).

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