

Captopril Tablets USP **25mg/50mg/100mg Taj Pharma** (Captopril)

Package leaflet: Information for the patient

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 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.

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

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 Captopril Tablets:

- If you are allergic (hypersensitive) to captopril, any of the other ingredients in these tablets or other ACE inhibitors (*see Section 6 and end of Section 2*).
- If you have ever had a reaction which included swelling of the hands, lips face or tongue where the cause was unknown.
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- If you are more than 3 months pregnant. (It is also better to avoid Captopril tablets in early pregnancy – see pregnancy section.)

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

Talk to your doctor, pharmacist or nurse before using Captopril tablets:

- If you suffer from kidney disease.
- If you suffer from liver disease. If you are undergoing dialysis.
- If you have suffered from heart disease, in particular problems with the valves of the heart.
- If you are receiving immuno-suppressant therapy.
- If you have recently suffered from excessive diarrhoea or vomiting. If you have diabetes.

- If you suffer from any collagen vascular diseases such as 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 anesthetic.
 - If you are going to have desensitization treatment, e.g. for an allergic reaction to wasp or bee stings.
 - If you are about to have treatment for the removal of cholesterol from your blood by a machine, (called LDL apheresis).
 - You must tell your doctor if you think you are (or might become) pregnant. Captopril tablet is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant it may cause serious harm to your baby if used at that stage (see pregnancy section).
 - Some Afro-Caribbean patients may require higher doses of Captopril to obtain an adequate reduction in blood pressure.
- 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 Tablets”

Other medicines and Captopril Tablets:

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 Captopril Tablets” and “Warnings and precautions”).

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

- Diuretics (water tablets).
 - Potassium supplements or salt substitutes containing potassium (e.g. triamterene, amiloride and spironolactone).
 - 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).
- 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.

Taking Captopril Tablets with food or drink

Captopril Tablets 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 and breast-feeding

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 tablets 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 tablet 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), 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.

Ask your doctor or pharmacist for advice before taking any medicine.

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.

Important information about some of the ingredients of Captopril Tablets

These tablets contain Lactose. If you have been told by your doctor that if you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Captopril Tablets

Always take this medicine exactly how your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow the tablets orally with a glass of water.

The usual doses are:

For the treatment of high blood pressure (hypertension): The usual starting dose is 12.5 mg-25 mg twice a day. If required, your doctor may gradually increase this dose to 100 mg-150 mg a day. Your doctor may prescribe another medicine to lower your blood pressure.

In Heart failure: The usual starting dose is 6.25 mg -12.5 mg 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 usual starting dose is 6.25 mg, which will be then gradually increased by your doctor to a maximum of 150 mg a day..

For the treatment of diabetic patients with kidney disease: The usual dose is 75-100 mg a day.

Elderly patients (over 65 years):

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. 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 the child's weight in kilograms.

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

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 tablets. If this happens to you, lie down until these symptoms disappear.

You should try to take Captopril tablets 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 tablets 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 Captopril Tablets

Do not stop taking this medicine without telling your doctor first.

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, lips or tongue
Difficulty in breathing,

- A sudden, unexpected rash or burning, red or peeling skin.
- Sore throat or fever,
- Severe dizziness or fainting, Severe stomach pain,
- Unusually fast or irregular heartbeat,
- Yellowing of the skin and/or eyes (jaundice).

Common side effects (affecting between 1 in 10 and 1 in 100 people)

- Dizziness, Itching, Rashes,
- Hair loss,
- Dry mouth,
- Sleep problems,
- Diarrhoea or constipation,
- Dry, irritating cough,
- Loss of taste (usually reversible on stopping treatment),
- Upset stomach, feeling sick, vomiting, abdominal pain,
- Shortness of breath
- 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)

- Mouth ulcers, Drowsiness,
- Changes in frequency of passing urine,
- Kidney disorders or failure

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
- Stevens-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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. How to store Captopril Tablets

- Keep this medicine out of the sight and reach of children
- Do not store above 25°C. Store in the original package.
- Do not use this medicine after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.
- 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 protect the environment.

6. Contents of the pack and other information

What Captopril Tablets contains

The **active** substance is captopril.

a) Each uncoated tablet contains:

Captopril USP	25mg
Excipients	q.s.

b) Each uncoated tablet contains:

Captopril USP	50mg
Excipients	q.s.



c) Each uncoated tablet contains:

Captopril USP 100mg
Excipients q.s.

The **other** ingredients are lactose monohydrate, pregelatinised starch, stearic acid and microcrystalline cellulose 102 (*see Section 2 'Important information about some of the ingredients of Captopril Tablets'*).

What Captopril Tablets looks like and contents of the pack

White to off-white, round, flat, beveled edged , uncoated tablet.

AL/PVC or PVC/PVdC/ AL Blister packs

Pack sizes: 7, 14, 28, 30, 50, 90, 100 and 500 tablets.

Not all pack sizes may be marketed.

7. MANUFACTURED IN INDIA BY:

TAJ PHARMACEUTICALS LTD.

Mumbai, India

Unit No. 214.Old Bake House,

Maharashtra chambers of Commerce Lane,

Fort, Mumbai - 400001

at:Gujarat, INDIA.

Customer Service and Product Inquiries:

1-800-TRY-FIRST (1-800-222-434 & 1-800-222-825)

Monday through Saturday 9:00 a.m. to 7:00 p.m.

EST

E-mail: tajgroup@tajpharma.com