

Package Leaflet: Information for the user

Capoten[®] 25mg Tablets Capoten[®] 50mg Tablets

Captopril

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 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 Capoten is and what it is used for
2. What you need to know before you take Capoten
3. How to take Capoten
4. Possible side effects
5. How to store Capoten
6. Contents of the pack and other information

1. WHAT CAPOTEN IS AND WHAT IT IS USED FOR

The name of this medicine is Capoten. Each tablet contains captopril (25mg or 50mg) as the active ingredient. Capoten 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.

Capoten 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. Capoten works by lowering your blood pressure which reduces this risk.

Capoten can also help people whose heart no longer pumps blood as well as it once did. This condition is known as heart failure.

Capoten 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, Capoten can be used for the treatment of kidney disease in patients with diabetes.

2. What you need to know before you take Capoten

Do not take Capoten tablets:

- If you are allergic to captopril or any of the other ingredients of this medicine (listed in section 6),
- If you are more than 3 months pregnant. (It is also better to avoid Capoten in early pregnancy – see pregnancy section.),
- If you have ever had an **allergic** reaction to any ingredients of Capoten or to any other medicines, including ACE inhibitors,
- If you have ever had a **reaction** which included swelling of the hands, lips, face or tongue where the cause is unknown,
- If you suffer from any **auto-immune disease** (e.g. rheumatoid arthritis, systemic lupus erythematosus or scleroderma).

If any of the above affects you, or you are unsure if they do, tell your doctor who will be able to advise you.

Warnings and precautions

Talk to your doctor or pharmacist before taking Capoten.

You must tell your doctor if you:

- Think you are (or might become) pregnant. Capoten 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).
- Suffer from kidney disease,
- Suffer from liver disease,
- Are undergoing dialysis,
- Suffer from heart disease, in particular problems with the valves of the heart,
- Have diabetes,
- Have recently suffered from excessive vomiting or diarrhoea,
- Are receiving immuno-suppressant therapy.

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 Capoten. 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 Capoten.

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

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

Other medicines and Capoten

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important to tell your doctor if you are taking any of the following:

- Non steroidal anti-inflammatory painkillers **NSAIDs** (e.g. indomethacin, ibuprofen),
- **Immunosuppressants** (e.g. azathioprine and cyclophosphamide),
- Potassium supplements, salt substitutes containing potassium or any other medicines which can increase potassium in your body, e.g. (amiloride, spironolactone),
- **Water tablets** (diuretics),
- Medicines for **gout** (e.g. allopurinol),
- Medicines for **diabetes** (as the amount you need to use may have to be changed while taking Capoten),
- Medicines that cause dilation of the **blood vessels** (e.g. minoxidil, clonidine),
- Medicines to treat **mental health problems** including depression (such as lithium or amitriptyline),
- Any other medicines to treat **high blood pressure** (e.g. beta-blockers such as propranolol, atenolol or calcium channel blockers such as amlodipine, nifedipine),
- Any medicine that may be used during and after a **heart attack**.

Capoten with food and drink

Capoten can be taken with or without food.

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 Capoten before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Capoten. Capoten 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 Capoten. In the case of an older baby your doctor should advise you on the benefits and risks of taking Capoten 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 Capoten as there may be a sudden fall in your blood pressure.

Driving and using machines

Capoten 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 Capoten tablets, you should not drive or use machinery.

Capoten contains lactose

Capoten contains 25mg to 50mg **lactose** which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Capoten

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 usual doses are:

For the treatment of high blood pressure

The usual 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 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 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 6.25mg, 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 usual dose is 75 - 100mg a day.

For children

The starting dose is 0.3mg/kg bodyweight, which may be increased gradually by the doctor.

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

The starting dose should be 0.15mg/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 Capoten. If this happens to you, lie down until these symptoms disappear. You should try to take Capoten at about the same time each morning. It can be taken before, during or after meals.

Even if you feel well continue to take Capoten until your doctor tells you otherwise.

If you take more Capoten than you should

If you or any one else takes too many tablets you should go to your nearest hospital emergency department or tell your doctor immediately. Take the carton and any remaining tablets you have with you.

If you forget to take Capoten

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 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 Capoten 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
- Changes in the way things taste,
- Shortness of breath
- Dry mouth,
- Sleep problems,
- Diarrhoea or constipation,
- Dry, irritating cough,
- Upset stomach, sickness, abdominal pain

Uncommon side effects (affecting between 1 in 100 and 1 in 1000 people)

- Fast, irregular, louder heartbeat,
- Chest pain,
- Low blood pressure,
- Reduced blood flow to the hands and feet (e.g. Raynaud syndrome),
- Tiredness,
- Generally feeling unwell,
- Looking pale,
- Swelling of the eyes and lips (angioedema).
- Flushing,

Rare side effects (affecting between 1 in 1000 and 1 in 10,000 people)

- Loss of appetite,
- Drowsiness,
- Headache,
- Changes in frequency of passing urine.
- Pins and needles, numbness or tingling,
- Mouth ulcers,
- 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,
- Stomach ulcers,
- 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 chemicals in the blood or lymphatic systems (e.g. 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. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

IRELAND: FREEPOST, Pharmacovigilance Section, Irish Medicines Board, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2, Ireland.

Tel: +353 1 6764971, Fax: +353 1 6762517, Website: www.imb.ie, e-mail: imbpharmacovigilance@imb.ie

5. HOW TO STORE Capoten

- Do not store above 25°C. Store in the original package to protect from moisture, and make sure they do not get too hot or damp; so do not leave your tablets near a radiator, on a window sill or in the bathroom.

Please check the expiry date of this product, shown on the outer packaging. Do not use the tablets after this date.

Keep this medicine out of sight and reach of children.

If your doctor decides to stop the tablets, ask your pharmacist to tell you what to do with any you have left.

6. Contents of the pack and other information

What Capoten contains

- The active substance is captopril (either 25 or 50mg).
- The other ingredients are lactose monohydrate, maize starch, microcrystalline cellulose and stearic acid.

What Capoten looks like and the contents of the pack

Capoten 25mg tablets are slightly mottled, white, square tablets. They are engraved 'Squibb' and '452' on one side and have quadrisection bars on the other or are slightly mottled, white, square tablets engraved with "25" on one side with quadrisection bars on the other side.

Capoten Tablets 50mg are slightly mottled, white, oval and biconvex tablets. They are engraved with 'Squibb' and '482' on one side, and have a breakline on the other side or white, oval, biconvex tablet, with "50" engraved on one side and scored on the other side.

Pack sizes:

Capoten 25mg tablets are available in blister packs in pack sizes of 56 and 60 tablets.

Capoten 50mg tablets are available in blister packs in pack sizes of 30 and 56 tablets.

MANUFACTURERS

Capoten Tablets are manufactured by Bristol-Myers Squibb, Avenue du Dr. Gilles, 28230 Epernon, France, or by BRISTOL-MYERS SQUIBB, S.r.l., Contrada Fontana del Ceraso, 03012 Anagni, Frosinone, Italy.

Product Procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath

PARALLEL PRODUCT AUTHORISATION NUMBER:

Capoten Tablets 25mg – PPA 465/2/1

Capoten Tablets 50mg – PPA 465/2/2

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Date of Leaflet Preparation by PCO Manufacturing: November 2013