

Package Leaflet: Information for the user

CAPOTEN™ 25 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, 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 25 mg captopril 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:

- 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 other ACE inhibitors.
- if you have ever had a **reaction** which included swelling of the hands, lips, face or tongue where the cause was unknown.
- if you suffer from any **auto-immune disease** (e.g. rheumatoid arthritis, systemic lupus erythematosus or scleroderma).
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

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.

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 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.

Children and adolescents

Safety and effectiveness in children have not been established. Newborns and infants may be at greater risk to the low blood pressure side-effects of Capoten

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**.

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 Capoten' and 'Warnings and precautions'.

Capoten with food and drink

Capoten can be taken with or without food. Your doctor may advise you to limit the amount of salt in your diet while taking Capoten.

Moderate amounts of alcohol will not affect Capoten, however, you should check with your doctor first to see if drinking is advisable for you.

Pregnancy and breastfeeding

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 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 25 mg **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 recommended doses are:

For the treatment of high blood pressure

The usual starting dose is 12.5 – 25 mg twice a day. Your doctor may gradually increase this dose to 100 – 150 mg 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 – 12.5 mg two or three times a day. Your doctor may gradually increase this dose to a maximum of 150 mg a day.

After a heart attack

The usual starting dose is 6.25 mg, which will then be 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.

For children

The starting dose is 0.3 mg/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 0.15 mg/kg bodyweight.

Doctors sometimes prescribe different doses to the above and if this applies to you, you should discuss it with your doctor. The tablets can be broken in half for a 12.5 mg dose or quarters for 6.25 mg dose.

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 a forgotten dose.

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 | • Dry mouth |
| • Itching | • Sleep problems |
| • Rashes | • Diarrhoea or constipation |
| • Hair loss | • Dry, irritating cough |
| • Changes in the way things taste | • Upset stomach, feeling sick, vomiting, abdominal pain |
| • Shortness of breath | • Stomach ulcers |
| • Indigestion | |

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

- | | |
|--|--|
| • Headache | • Pins and needles, numbness or tingling |
| • Fast, irregular, louder heartbeat | • Tiredness |
| • Chest pain | • Generally feeling unwell |
| • Low blood pressure | • Looking pale |
| • Reduced blood flow to the hands and feet (e.g. Raynaud's phenomenon) | • Swelling of the eyes and lips (angioedema) |
| • Flushing | • Loss of appetite |
| • Muscle weakness | |

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

- | | |
|---|-------------------------------|
| • Drowsiness | • Mouth ulcers |
| • 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 | • Liver damage, inflammation of the liver or jaundice |
| • Confusion, depression, fainting | • Muscle pain |
| • Mini-stroke | • Joint pain |
| • Blurred vision | • Wheezing or difficulty breathing |
| • Heart problems including heart attack, and chest infections | • Rashes or skin reactions |
| • Inflammation of the pancreas | • Swelling of breast tissue in men |
| • Runny nose | • Fever |
| • Swollen tongue | • Sensitivity of the skin to light |
| • Impotence | • Changes in levels of cells and/or chemicals in the blood or lymphatic systems (e.g. red or white blood cells, potassium, sodium, sugars) |
| • Stevens-Johnson syndrome (a serious illness with blistering of the skin, mouth, eyes and genitals) | |

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 via:

HPRA Pharmacovigilance
Earlsfort Terrace
IRL-Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Capoten

Keep this medicine out of the sight and reach of children.

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.

Do not use this medicine after the expiry date which is stated on the 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 Capoten contains

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

What Capoten looks like and contents of the pack

Capoten 25 mg tablets are white, square, biconvex tablets, embossed with “25” on one side and cross scored on the other side. The score line is to facilitate breaking for the ease of swallowing and to divide into equal doses of 12.5 mg (half tablet) or 6.25 mg (quarter tablet). The tablets come in blister packs of 28 tablets.

Marketing Authorisation Holder and Manufacturer:

Bristol-Myers Squibb Pharmaceuticals Ltd
Swords,
County Dublin, Ireland
Tel: 1 800 749 749

Manufacturer:

Bristol-Myers Squibb, S.r.l.
Contrada Fontana del Ceraso
03012 Anagni (FR)
Italy

Date of last revision:

June 2016