

CAPOTEN®

captopril

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking Capoten. This leaflet answers some common questions about Capoten. It does not contain all the available information. Some of the information it contains may not apply to you. It does not take the place of talking to your doctor or pharmacist.

Always follow the instructions that your doctor and pharmacist give you about Capoten.

Ask your doctor or pharmacist if you have any concerns about taking Capoten.

Keep this leaflet with the medicine.

You may need to read it again

What Capoten is used for

Capoten is used for treating high blood pressure (hypertension), certain heart conditions, and certain kidney conditions associated with diabetes. These are long term (chronic diseases) so it is important that you continue to take your Capoten every day.

Capoten contains captopril. Captopril belongs to a class of medicines known as Angiotensin Converting Enzyme (ACE) inhibitors. ACE inhibitors work to lower your blood pressure to normal levels if it is too high. Capoten also acts to help your heart or kidneys to work better. Your doctor will tell you why you need to take Capoten. Never let anyone else take your medicine. It may harm them, even if

their signs of illness are the same as yours.

There is no evidence that it is addictive or habit forming.

This medicine is only available only with a doctor's prescription.

Capoten is not recommended for use in children as there have been not enough studies of its effects in children. However it may be necessary for a child with hypertension and kidney problems to take this medicine, if this is the case your doctor will discuss all the possible risks and benefits to the child before starting therapy.

Before you take Capoten

When you must not take it

You must not take Capoten if:

- you are pregnant or may become pregnant
- you have ever had medical conditions known as idiopathic angioedema or hereditary angioedema
- you have ever had an allergy to Capoten or any of the ingredients listed at the end of this leaflet, or to another ACE inhibitor
- you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- you 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.

If any of the above applies to you, you should ask your doctor's advice before taking this medicine.

Symptoms of an allergic reaction to Capoten may include

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty breathing or swelling of any other parts of the body
- rash, itching or hives on the skin

Do not take Capoten after the expiry date printed on the pack.

If you take Capoten after this date or if Capoten starts to change in appearance, colour or taste, it may not work as well.

Before you start to take it

Before you take Capoten for the first time, tell your doctor if you:

- are pregnant or may become pregnant
- are breastfeeding or intend to breastfeed
- have any other medical problems, particularly diabetes, systemic lupus erythematosus, scleroderma, neutropenia (low white blood cell count), have had a heart attack, heart failure, ischaemic heart disease or cerebrovascular disease
- take any other medicines or drugs, including any immunosuppressant medicine

- have had an allergy to Capoten or any of its additives, or to another ACE inhibitor
- have kidney disease, a single kidney or are undergoing dialysis
- liver disease now or in the past
- are dehydrated, have had a recent bout of vomiting or diarrhoea or are taking a diuretic medicine (water tablets)

Taking other medicines

Some medicines can affect the way Capoten works.

You should always tell your doctor about any other medicines that you take, even if you have bought the medicines without a doctor's prescription. It is especially important that you tell your doctor if you are taking any of the following:

- water tablets or diuretics (for example Lasix®, Urex®, Natrilix®, Moduretic®)
- lithium or lithium-containing preparations (for example Lithicarb®, Priadel®)
- potassium tablets (for example SPAN-K®, SLOW-K® or K-MAG®)
- potassium-containing salt substitutes (for example PRESSOR-K®)
- antacids
- any other medicine for high blood pressure
- any medicine for angina
- procainamide, a medicine for irregular heartbeat
- medicines for cancer treatment or in patients who had a transplantation (cytostatic agents/ immunosuppressant agents), such as fluorouracil, methotrexate, ciclosporin and azathioprine
- allopurinol, a medicine used to treat gout
- **if you are taking Capoten for high blood pressure do not take any medicine (including**

ones bought without a prescription) for appetite control, asthma, colds, coughs, hay fever or sinus problems unless you have discussed the medicine with your doctor or pharmacist.

- anti-inflammatory medicines (these are used to relieve pain, swelling and other symptoms of inflammation, including arthritis) and include nonsteroidal anti-inflammatory agents - NSAIDs (for example Voltaren, Indocid) and COX-2 inhibitors (for example Celebrex).
Taking a combination of Capoten with a thiazide diuretic (fluid tablet) and an anti-inflammatory medicine may damage your kidneys.

Your doctor may need to change your dose and/or to take other precautions:

If you are taking an angiotensin II receptor blocker (ARB) oraliskiren (see also “*When you must not take it*”).

Your doctor will decide whether your treatment needs to be altered or whether you should have check ups or blood tests more frequently.

How to take it

How much to take

Capoten is usually taken at a dose of 12.5 to 50mg two or three times per day. Treatment may be started with low doses of Capoten, particularly if you have heart failure. Your doctor will decide which dose is right for you.

How to take it

Swallow your tablets with a glass of water.

When to take it

Preferably take Capoten one hour before meals.

If you forget to take it

If you forget to take one or more doses: take your next dose at the normal time and in the normal amount.

Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting an unwanted side effect.

Ask your doctor or pharmacist if you are not sure what to do.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

How long to take it

Capoten is used to treat long term (chronic) diseases, so it is important to continue taking Capoten every day until your doctor tells you to stop.

Do not stop taking your tablets because you are feeling better.

If you take too much (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to casualty at your nearest hospital, if you think that you or any one else may have taken too much Capoten. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention

While you are using Capoten

Things you must do

- **If you become pregnant while taking Capoten tell your doctor immediately**
- **Have your blood pressure checked when your doctor tells you to, to make sure the medicine is working**
- **If you are about to start on any new medicine, tell your**

doctor and pharmacist that you are taking Capoten.

- **If you plan to have surgery (even at the dentist) that needs an anaesthetic, or are having some other hospital treatment, make sure that you tell your doctor or dentist that you are taking this medicine**
- **Make sure you drink enough water during exercise and hot weather when you are taking it, especially if you sweat a lot**
If you do not drink enough water while taking Capoten, you may faint or feel light-headed or sick. This is because your body does not have enough fluid and your blood pressure is low. If you continue to feel unwell, tell your doctor.
- **If you have excessive vomiting and/or diarrhoea while taking Capoten, tell your doctor**
This can also mean that you are losing too much water and your blood pressure may become too low.
- **Have any blood tests that your doctor asks you to**

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

Things you must not do

Do not stop taking Capoten without first checking with your doctor.

Things to be careful of

Capoten can cause dizziness, lightheadedness or fainting, especially when you get up from bed or from a chair.

Always get up slowly to allow your body to adjust. Be careful the first time you take Capoten.

If you are elderly, you should be particularly careful when you get up from bed or from a chair. If

you are elderly, you should also be particularly careful when you are taking Capoten for the first time.

Be careful driving or operating machinery until you know how this medicine affects you.

As with other ACE inhibitors, Capoten can cause dizziness or lightheadedness in some people, especially after the first dose. Make sure you know how Capoten affects you before you drive a car or operate machinery, or do any thing else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Capoten.

All medicines can sometimes cause unwanted effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- lightheadedness;
- dizziness;
- headache;
- tiredness;
- dry cough;
- dry mouth;
- feeling sick;
- diarrhoea or constipation;
- stomach pains;
- taste disturbances;
- sleep disorders;
- hair loss;
- itching or a red rash;
- muscle cramps.

If too much potassium builds up in your body you may experience the following:

- confusion;
- irregular heartbeat;
- nervousness;

- numbness or tingling of the hands, feet or lips;
- shortness of breath or difficulty breathing;
- weakness or heaviness of legs.

These are the more common side effects of Capoten.

You should stop taking Capoten and call your doctor immediately or go to your nearest hospital if you get any of the following side effects:

- swollen face, lips, mouth, tongue, throat, hands, or feet
- if you faint or if your skin and/or eyes turns yellow;
- sore throat and fever;
- chest pain;
- severe dizziness and fainting
- difficulty breathing or swallowing;
- itchy skin and/or a rash;
- not urinating (passing water) as much as usual.
- 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)

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using it

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the pack they will not keep as well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Keep Capoten Oral Solution in a refrigerator at 2 to 8°C.

Return any unused solution to your pharmacist 28 days after the bottle is first opened. After this date the solution should not be taken.

Keep Capoten and all medicines out of reach of children.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Distributor and Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

This leaflet was revised in October 2023.

Product description

What it looks like

- Capoten 25mg tablets - white, square and scored (AUST R 19247).
Each carton contains 90 tablets.
- Capoten 50mg tablets - white, oval and scored (AUST R 19248).
Each carton contains 90 tablets.
- Capoten oral solution 5mg/mL - clear, colourless solution, flavour-free (AUST R 68962).
Each bottle contains 95mL.

Active ingredients

- Capoten 25mg tablets - 25mg captopril per tablet.
- Capoten 50mg tablets - 50mg captopril per tablet.
- Capoten oral solution 5mg/mL - 5mg captopril per mL.

Additives

Capoten tablets also contain lactose, microcrystalline cellulose, maize starch and stearic acid.

Capoten oral solution also contains sodium citrate dihydrate, citric acid, disodium edetate, sodium benzoate and water.