

DP-Captopril

Captopril

5 mg/mL Oral Solution

What is in this leaflet

Please read this leaflet carefully before you start taking DP-Captopril

This leaflet answers some common questions about DP-Captopril. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking DP-Captopril against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What DP-Captopril is used for

DP-Captopril is used for the treatment of 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 DP-Captopril every day.

DP-Captopril belongs to a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors. It works by widening your blood vessels, which reduces pressure in the vessels. This makes it easier for your heart to pump blood around your body, and helps your heart or kidneys to work better.

Your doctor may have prescribed DP-Captopril for another reason.

Ask your doctor if you have any questions about why DP-Captopril has been prescribed for you.

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

Before you use DP-Captopril

When you must not take it

Do not take DP-Captopril if you have an allergy to:

- any medicine containing captopril, or a class of medicines called ACE inhibitors.
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing
- shortness of breath
- swelling of the face, tongue, lips, or
- other parts of the body
- hives on the skin, rash, or itching.

Do not take DP-Captopril if you have a history of blood vessel swelling with previous treatment with an ACE inhibitor.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not take this medicine if you have diabetes or impaired kidney function and you are being treated with a blood pressure lowering medicine containing aliskiren.

Do not take this medicine if 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 risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.

Do not take it after the expiry date (EXP) printed on the back. If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking DP-Captopril, talk to your doctor.

Before you start to take it

Tell your doctor if:

- 1. you have allergies to:**
 - Any other medicines including captopril or any other ACE inhibitors.
 - Any of the excipients of DP-Captopril.
 - Any other substances, such as foods, preservatives or dyes.
- 2. you have, or have had, the following medical conditions:**
 - kidney disease, a single kidney or are undergoing dialysis.
 - Idiopathic or Hereditary angioedema (Recurrent swelling)
 - diabetes
 - heart disease, have had a heart attack, heart failure, ischaemic heart disease.
 - systemic lupus erythematosus, scleroderma
 - neutropenia (low white blood cell count).
 - liver disease now or in the past.
 - Are dehydrated, have had a recent bout of vomiting or diarrhoea.
- 3. you take an angiotensin II receptor blocker (ARBs) (also known as sartan).**
- 4. you take any medicines belonging to class mTOR inhibitors (used to avoid rejection of transplanted organs) such as sirolimus, everolimus.**
- 5. you are to have desensitisation treatment for wasp or bee stings.**
- 6. you are pregnant or intend to become pregnant.**
- 7. you are breastfeeding planning to breastfeed.** It is known captopril passes into breastmilk. Your doctor can discuss with you the risks and benefits involved.
- 8. 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 DP-Captopril as there may be sudden fall in your blood pressure.

- 9. You have any blood or urine test as DP-Captopril may interfere with the results of some tests.**

If you have not told your doctor about any of the above, tell them before you start taking DP-Captopril.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking DP-Captopril.

Some medicines may interfere DP-Captopril. These include:

- water tablets or diuretics (such as bendroflumethiazide, indapamide), in particular that so-called potassium sparing such as amiloride, spironolactone.
- potassium supplements, tablets or salt substitutes containing potassium (such as antacids).
- medicines that can increase potassium in your body such as heparin.
- any other medicines to treat high blood pressure.
- medicine used to treat angina such as glyceryl trinitrate or other nitrates.
- lithium or lithium-containing preparations.
- anti-inflammatory medicines (these are used to relieve pain, swelling and other symptoms of inflammation, including arthritis) and include nonsteroidal anti-inflammatory agents such as ibuprofen, diclofenac.
- medicines which are most often used to avoid rejection of transplanted organs such as sirolimus, everolimus.
- medicine for gout such as allopurinol.
- if you are taking DP-Captopril 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.

- taking a combination of DP-Captopril with a thiazide diuretic (fluid tablet) and an anti-inflammatory medicine may damage your kidneys.
- Procainamide, cytostatic or immune-suppressive medicines may lead to increased risk of white blood cell loss.
- Tricyclic antidepressants, neuroleptics, baclofen and amifostine can increase the blood pressure lowering effect of captopril.
- The effect of antidiabetic medicines may be increased if combined with captopril (Eg. Glibenclamide, Gliclazide, Glipizide and Vidagliptin)
- Aliskiren containing products: do not take captopril if you have diabetes mellitus or kidney problems.
- Do not take captopril if you are on a sacubitril/valsartan combination product.
- Do not take captopril if you are taking an angiotensin II receptor blocker (ARB).
- Use of gold in combination with captopril may cause flushing, dizziness, nausea, vomiting and a drop in blood pressure.

These medicines may be affected by DP-Captopril or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking DP-Captopril and whether you should have check-ups or blood tests more frequently.

How to use DP-Captopril

How much to take

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

Follow all directions given to you by your doctor or pharmacist carefully. Your doctor may have prescribed a different dose.

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

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

If you take the wrong dose, DP-Captopril may not work as well, and your condition may not improve.

How to take it

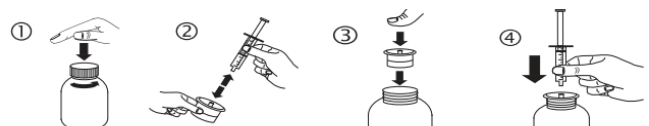
Your doctor or pharmacist will show you how to administer this medicine by dosing cup or syringe. The box containing this medicine will also contain a 3 mL dosing syringe, a syringe adaptor and a 30 mL dosing cup.

The 3 mL syringe is marked with a scale showing mL. The graduation is in steps of 0.25 mL equivalent to 1.25 mg DP-Captopril oral solution.

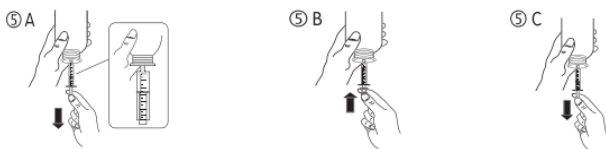
The 30 mL dosing cup, each numbered increment is 5 mL equivalent to 25 mg DP-Captopril Oral Solution and having additional increments of 2.5 mL (12.5 mg) and 7.5 mL (37.5 mg). On another side is a scale showing teaspoon (TSP) in steps of half teaspoon ($\frac{1}{2}$ TSP) equivalent to 2.5 mL or 12.5 mg captopril. The TSP scale measures up to 4 teaspoons (4 TSP) equivalent to 20 mL or 100 mg captopril.

How to use dosing syringe device

1. open the bottle: press the cap and turn it anticlockwise (figure 1).
2. Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



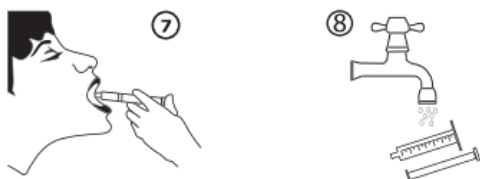
- Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (mL) prescribed by your doctor (figure 5C).



- Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



- Empty the contents of the syringe into the patient's mouth by gently pushing the piston to the bottom of the syringe (figure 7). Close the bottle with the plastic screw cap. Do not remove the syringe adaptor from the bottle. Wash the syringe with water (figure 8).



When to take it

DP-Captopril should be taken one hour before meals.

Take DP-Captopril at about the same time each day. Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take your medicine.

How long to take it

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

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

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 that you missed. This may increase the chance of unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

While you are taking DP-Captopril

Things you must do

Have your blood pressure checked when your doctor tells you to, to make sure DP-Captopril is working.

If you are about to start on any new medicine, tell your doctor and pharmacist that you are taking DP-Captopril.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking DP-Captopril.

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 DP-Captopril.

Make sure you drink enough water during exercise and hot weather when you are taking DP-Captopril.

If you do not drink enough water while taking DP-Captopril, 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 DP-Captopril, tell your doctor. This can also mean that you are losing too much water and your blood pressure may become too low.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not give DP-Captopril to anyone else, even if they have the same condition as you.

Do not stop taking DP-Captopril or lower the dosage, without checking with your doctor.

Things to be careful of

DP-Captopril can cause dizziness, light-headedness 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 DP-Captopril. 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 DP-Captopril for the first time.

Be careful driving or operating machinery until you know how DP-Captopril affects you. It may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy.

Be careful if you are over 65, unwell or taking other medicines. Some people may experience side effects such as drowsiness, confusion, dizziness, and unsteadiness, which may increase the risk of a fall.

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness or light-headedness may be worse.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

DP-Captopril is not recommended for use in children as there have not been enough studies of its effects in children and oliguria is a risk in premature infants and leukopenia in children with kidney problems. However, it may be necessary for a child with hypertension and kidney problems to take DP-Captopril. If this is the case, your doctor will discuss all the possible risks and benefits to the child before starting therapy.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766) or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much DP-Captopril.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

If you are over 65 years of age you may have an increased chance of getting side effects. (If there is an increased risk of side effects in the elderly).

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- light-headedness or dizziness
- headache
- tiredness
- dry, irritating cough
- dry mouth
- taste disturbances
- diarrhoea or constipation
- upset stomach, feeling sick, vomiting, abdominal pain.
- muscle cramps
- sleep disturbance
- Skin rash

These are the more common side effects of DP-Captopril.

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

- confusion
- irregular heartbeat
- nervousness
- numbness
- tingling of the hands, feet, or lips
- shortness of breath
- difficulty breathing
- weakness
- heaviness of legs

If any of the following happen, stop taking DP-Captopril and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- Swelling of the face, lips, mouth, hands, tongue or throat which may cause difficulty in swallowing or breathing.
- A sudden, unexpected rash or burning, red or peeling skin.
- Severe dizziness or fainting.
- Severe stomach pain.

- Yellowing of the skin and/or eyes (jaundice).
- Sore throat and fever.
- Chest pain.
- Unusually fast or irregular heartbeat.
- Not urinating (passing water) as much as usual.
- Feeling tired or weak.
- Experience cold feet or hands.
- Feel short of breath.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to DP-Captopril. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor if you notice any other effects. Other adverse effects not listed above may also occur in some patients.

After taking DP-Captopril

Storage

Store DP-Captopril Oral Solution below 30°C. Discard 21 days after first opening.

Do not store DP-Captopril in the bathroom or near a sink. Do not leave it in the car or on a windowsill. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Return any unused solution to your pharmacist 21 days after the bottle is first opened. After this date the solution should not be taken.

Product description

What it looks like

DP-Captopril oral solution 5 mg/mL is a clear, colourless, flavour-free solution. DP-Captopril is available in pack sizes of either 95 mL or 100 mL. Not all pack sizes may be marketed.

Ingredients

Active ingredient(s):

Captopril 5 mg/mL

Inactive ingredients:

- sodium citrate
- citric acid
- disodium edetate
- sodium benzoate
- water

Contains benzoates.

Sponsor details

DP-Captopril is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

P O Box 45 027

Auckland 0651

New Zealand

Phone: (09) 835 0660

Date of preparation

05 April 2023

(based on data sheet dated 05 April 2023)