

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking ZEDACE?

ZEDACE contains the active ingredient captopril. ZEDACE is for treating high blood pressure (hypertension), certain heart conditions, and certain kidney conditions associated with diabetes. For more information, see Section [1. Why am I taking ZEDACE?](#) in the full CMI.

2. What should I know before I take ZEDACE?

Do not take if you have ever had an allergic reaction to ZEDACE or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take ZEDACE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZEDACE and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take ZEDACE?

- The usual dose ranges from 12.5 mg to 50 mg, two or three times a day. However, your doctor may ask you to take a different dose depending on your condition and your response to ZEDACE.
- Swallow the tablets with a glass of water.

More instructions can be found in Section [4. How do I take ZEDACE?](#) in the full CMI.

5. What should I know while taking ZEDACE?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking ZEDACE. • Have your blood pressure checked when your doctor tells you to, to make sure ZEDACE is working. • Make sure you drink enough water during exercise and hot weather, especially if you sweat a lot. • If you have severe vomiting or diarrhoea while taking ZEDACE, tell your doctor. • If you plan to have desensitisation therapy for an allergy (e.g. to an insect bite), tell your doctor that you are taking ZEDACE.
Things you should not do	• Do not take ZEDACE to treat any other complaints unless your doctor tells you to. • Do not give your medicine to anyone else, even if they have the same condition as you. • Do not stop taking your medicine or lower the dosage without checking with your doctor.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how ZEDACE affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Store below 25°C. • Keep your tablets in the blister pack until it is time to take them.

For more information, see Section [5. What should I know while taking ZEDACE?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects: dizziness; headache; tiredness; dry cough; dry mouth; feeling sick; stomach problems; taste disturbances; sleep disorders; hair and skin problems; muscle cramps; confusion; nervousness; irregular heartbeat; numbness or tingling in the hands; feet or lips; breathing problem; weakness or heaviness of the legs. **Serious side effects:** fast or irregular heartbeat; severe dizziness or fainting; skin and/or eyes turn yellow, allergy symptoms causing swallowing or breathing problem, skin problems (a very rare illness known as Stevens-Johnson syndrome); not urinating (passing water) as much as usual.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about taking ZEDACE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking ZEDACE.**

Where to find information in this leaflet:

1. [Why am I taking ZEDACE?](#)
2. [What should I know before I take ZEDACE?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take ZEDACE?](#)
5. [What should I know while taking ZEDACE?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking ZEDACE?

ZEDACE contains the active ingredient captopril. Captopril belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.

ACE inhibitors work to lower your blood pressure to normal levels if it is too high.

ZEDACE 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 ZEDACE every day. ZEDACE also acts to help your heart or kidneys to work better. Your doctor will tell you why you need to take ZEDACE. 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 ZEDACE is addictive or habit forming.

2. What should I know before I take ZEDACE?

Warnings

Do not take ZEDACE if you:

- are allergic to captopril, or to another ACE inhibitor, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can take this medicine.

- Symptoms of an allergic reaction to ZEDACE may include:
 - o shortness of breath, wheezing or difficulty breathing
 - o swelling of the face, lips, mouth, tongue or throat which may cause difficulty breathing or swelling of any other parts of the body
 - o rash, itching or hives on the skin

- are pregnant or may become pregnant
- have ever had medical conditions known as idiopathic angioedema or hereditary angioedema
- have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- 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.

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

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

Before you take ZEDACE for the first time, check with your doctor if you:

- have any other medical conditions 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 medicines or drugs for any other condition including any immunosuppressant medicine
- have had an allergy to ZEDACE 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)

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or may become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Use in children

ZEDACE 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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ZEDACE and affect how it works. It is especially important that you tell your doctor if you are taking any of the following:

- water tablets or diuretics
- lithium or lithium-containing preparations
- potassium tablets
- potassium-containing salt substitutes or other medicines associated with increases in serum potassium (e.g. trimethoprim containing medicines)
- 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 ZEDACE 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 non-steroidal anti-inflammatory agents – NSAIDs and COX-2 inhibitors.

Taking a combination of ZEDACE with a thiazide diuretic (fluid tablet) and an anti-inflammatory medicine may damage your kidneys.

- combination of ACE inhibitors and Vildagliptin

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 [2. What should I know before I take ZEDACE?](#)).

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZEDACE.

4. How do I take ZEDACE?

How much to take

- The dose varies from person to person.
- The usual dose ranges from 12.5 mg to 50 mg, two or three times a day. However, your doctor may ask you to take a different dose depending on your condition

(for example if you have kidney problems) and your response to ZEDACE.

- Treatment may be started with low doses of ZEDACE, particularly if you have heart failure. Your doctor will decide which dose is right for you.

When to take ZEDACE

- Take ZEDACE at about the same time each day.
Taking your tablets at the same time each day will have the best effect.
- Take ZEDACE on an empty stomach, preferably 1 hour before food.

Food can interfere with the absorption of ZEDACE.

How to take ZEDACE

- Swallow the tablets with a glass of water.

How long to take ZEDACE for

- ZEDACE is used to treat long term (chronic) diseases, so it is important to continue taking ZEDACE every day for as long as your doctor recommends.

To properly control your condition, it is important that you take ZEDACE every day, even if you feel well.

If you forget to take ZEDACE

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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.

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

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

If you take too much ZEDACE

If you think that you or anyone else has taken too much ZEDACE, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking ZEDACE?

Things you should do

- **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 ZEDACE.**

- **Make sure you drink enough water during exercise and hot weather, especially if you sweat a lot.**

If you do not drink enough water while taking ZEDACE, you may feel faint, 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 severe vomiting or diarrhoea while taking ZEDACE, tell your doctor.**

This may cause you to lose too much water and salt, and your blood pressure may become too low.

- **If you plan to have surgery, including dental surgery or other hospital treatment, tell your doctor or dentist that you are taking ZEDACE.**

This is especially important if your doctor or dentist will be giving you an anaesthetic.

- **If you plan to have desensitisation therapy for an allergy (e.g. to an insect bite), tell your doctor that you are taking ZEDACE.**

Your doctor may want to take special care.

- **If you have to have any urine tests, tell your doctor that you are taking ZEDACE.**

ZEDACE may affect the results of some tests.

- **Have any blood tests that your doctor asks you to.**
- **Keep all of your doctor's appointments so that your progress can be checked.**

Your doctor may want you to have some tests to check your kidneys, blood and other body functions.

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.

Call your doctor straight away if you:

- become pregnant while taking ZEDACE

Remind any doctor, dentist or pharmacist you visit that you are taking ZEDACE.

Things you should not do

- Do not take ZEDACE to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

Things to be careful of

- **Be careful getting up from a sitting or lying position.**

Dizziness, light-headedness or fainting may occur, especially when you get up quickly. This is more likely

to occur when you start taking ZEDACE, or if the dose is increased. Getting up slowly may help.

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 ZEDACE for the first time. These symptoms can be dangerous, especially in people with heart failure, angina or cerebrovascular disease.

If these symptoms continue or become worse, tell your doctor.

Lifestyle measures that help reduce heart disease risk

By following these simple measures, you can further reduce the risk from heart disease.

- Quit smoking and avoid second-hand smoke.
- Limit alcohol intake.
- Enjoy healthy eating by:
 - o eating plenty of vegetables and fruit;
 - o reducing your saturated fat intake (eat less fatty meats, full fat dairy products, butter, coconut and palm oils, most take-away foods, commercially-baked products).
- Be active. Progress, over time, to at least 30 minutes of moderate intensity physical activity on 5 or more days each week. Can be accumulated in shorter bouts of 10 minutes duration.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ZEDACE affects you.

ZEDACE may cause dizziness or light-headedness in some people, especially after the first dose. Make sure you know how ZEDACE affects you before you drive a car or operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Looking after your medicine

- Store below 25°C.
- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
- dizziness, light-headedness, faintness - headache - tiredness - dry cough - dry mouth - feeling sick - diarrhoea or constipation - stomach pain - 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, nervousness - irregular heartbeat - numbness or tingling in the hands, feet or lips - shortness of breath or difficulty breathing - weakness or heaviness of the legs	Speak to your doctor if you have any of these less serious side effects and they worry you. These are the more common side effects of ZEDACE.

Serious side effects

Serious side effects	What to do
- fast or irregular heartbeat - severe dizziness or fainting - your skin and/or eyes turns yellow	Stop taking ZEDACE and call your doctor straight away, or go straight

Serious side effects	What to do
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing - swelling of the hands or feet - shortness of breath, chest pain - sore throat and fever - itchy skin and/or a rash - pink or red itchy spots on the skin which may blister and progress to form raised, red, pale-centred marks - 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) - not urinating (passing water) as much as usual.	to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What ZEDACE contains

Active ingredient (main ingredient)	Captopril (25 mg and 50 mg)
Other ingredients (inactive ingredients)	- microcrystalline cellulose - lactose - maize starch - stearic acid - sodium starch glycollate
Potential allergens	- sugars as lactose - traces of phenylalanine

Do not take this medicine if you are allergic to any of these ingredients.

What ZEDACE looks like

- **25 mg** - white, octagonal, biconvex tablet, approx. 6.5 mm in diameter, quadrisected on one side with one character "C", "T", "2" and "5" in each quadrant and "G" on the reverse (AUST R 57370).
- **50 mg** - white oval, biconvex tablet, approx. 11.3 mm x 5.8 mm, with "CT/50" on one side and "G" on the reverse (AUST R 57371).

Each pack contains 90 tablets.

Who distributes ZEDACE

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in December 2025.

ZEDACE® is a Viatris company trade mark.

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