

ZEDACE®

captopril

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about ZEDACE.

It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking ZEDACE against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What ZEDACE is used for

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 contains 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 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 it is addictive or habit forming.

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

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.

Before you take ZEDACE

When you must not take it

You must not take ZEDACE 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 ZEDACE 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 ZEDACE 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 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 start to take it

Before you take ZEDACE 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 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)

Taking other medicines

Some medicines can affect the way ZEDACE 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®) 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 (for example Voltaren, Indocid) and COX-2 inhibitors (for example Celebrex).

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 "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 ZEDACE

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

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

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.

How to take it

Swallow the tablets with a glass of water.

When to take it

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 long to take it 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 it

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.

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 (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much ZEDACE. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking ZEDACE

Things you must do

- **If you become pregnant while taking ZEDACE, 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 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.

Things you must 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.

Be careful driving or operating machinery 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.

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

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:
 - eating plenty of vegetables and fruit;
 - 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.

Side effects

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

All medicines sometimes cause unwanted side effects.

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

- 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

These are the more common side effects of ZEDACE.

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

- fast or irregular heartbeat

- severe dizziness or fainting
- your skin and/or eyes turns yellow
- 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.

The above list includes 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 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 taking ZEDACE

Storage

Keep ZEDACE 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.

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

Do not store ZEDACE or any other medicine in the bathroom or

near a sink. Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

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.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ZEDACE tablets are available in two strengths:

- 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.
- 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.

Each pack contains 90 tablets.

Ingredients

The active ingredient in ZEDACE tablets is captopril:

- each ZEDACE 25 tablet contains 25 mg of captopril
- each ZEDACE 50 tablet contains 50 mg of captopril.

ZEDACE tablets also contain:

- microcrystalline cellulose
- lactose
- maize starch
- stearic acid
- sodium starch glycollate.

ZEDACE contains sugars as lactose and traces of phenylalanine.

Supplier

ZEDACE is supplied in Australia by:

**Alphapharm Pty Ltd trading as
Viartis**

Level 1, 30 The Bond,
30 - 34 Hickson Road
Millers Point NSW 2000
www.viartis.com.au
Phone: 1800 274 276

Australian registration numbers:

25 mg tablets - AUST R 57370

50 mg tablets - AUST R 57371

ZEDACE® is a Viartis company
trade mark

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