

Zedace

contains the active ingredient 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.

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

Do not take Zedace if you are allergic to:

- **you must not take Zedace if you are pregnant or may become pregnant**
- **medical conditions know as idiopathic angioedema or hereditary angioedema**
- **you must not take Zedace if 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**

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®)
- antacids
- any other medicine for high blood pressure
- any medicine for angina
- 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 nonsteroidal 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.

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.

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, for example, 1 hour before food.

Food can interfere with the absorption of Zedace.

How long to take it for

Keep taking Zedace 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.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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.

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, lightheaded 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, 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.

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.

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.

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 lightheadedness in some people. If this occurs, do not drive, operate machinery or do anything else that could be dangerous.

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. If you have

- **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.**
- **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 Zedace, 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 Zedace, 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 Zedace without first checking with your doctor.

Things to be careful of

Zedace 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 Zedace.

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.

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

As with other ACE inhibitors, Zedace can 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. 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 Zedace.

All medicines sometimes cause unwanted side effects.

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

- dizziness, lightheadedness, faintness
- headache
- tiredness
- dry cough
- feeling sick
- diarrhoea
- stomach pain
- taste disturbances
- muscle cramps.
- If too much potassium builds up in your body you may experience the following:
 - confusion, nervousness
 - irregular heart beat
 - 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 heart beat
- fainting within a few hours of taking a dose
- 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
- pink or red itchy spots on the skin which may blister and progress to form raised, red, pale-centred marks
- blisters or bleeding in the lips, eyes, mouth, nose and genitals.

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.

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 three strengths:

- 12.5 mg - white elongated tablet with partial bisect and "G" on one side and partial bisect and "C12.5" on the other side.
- 25 mg - white, octagonal, biconvex tablet, quadrasected 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, 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 12.5 tablet contains 12.5 mg of captopril
- each Zedace 25 tablet contains 25 mg of captopril
- each Zedace 50 tablet contains 50 mg of captopril.

Zedace tablets also contain:

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

The tablets are gluten free.

Supplier

Zedace is supplied by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Level 1, 30 The Bond,

30 - 34 Hickson Road

Millers Point NSW 2000

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

12.5 mg tablets - AUST R 57369

25 mg tablets - AUST R 57370

50 mg tablets - AUST R 57371

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