

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 to treat:

- * high blood pressure (hypertension)
- * heart failure
- * kidney problems in some people who have type 1 or insulin-dependent diabetes.

It is also used to improve the survival of some people who have had a heart attack.

Zedace belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.

ACE inhibitors lower blood pressure by widening blood vessels, making it easier for the heart to pump blood around the body.

Widening of the blood vessels also increases the supply of blood and oxygen to the heart. This allows your heart to cope better when you place extra demands on it, such as during exercise, so you may not get short of breath as easily (if you have heart failure).

By increasing the supply of oxygen to your heart, your heart does not have to work as hard, which may reduce the risk of further damage to the heart after a heart attack.

Zedace also improves blood flow through the kidneys, and as a result helps to slow down the kidney damage caused by type 1 insulin-dependent diabetes.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Zedace is not recommended for use in children.

Safety and effectiveness of Zedace in children have not been clearly established. However, Zedace may be necessary for a child with hypertension and kidney problems. If this is the case, your doctor will discuss all the possible risk and benefits to the child before starting treatment.

Zedace is available only with a doctor's prescription.

There is no evidence that Zedace is addictive.

Before you take Zedace

When you must not take it

Do not take Zedace if you are allergic to:

- * captopril or any other ACE inhibitor medicine
- * any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue, difficulty swallowing or breathing; wheezing or shortness of breath.

Do not take Zedace if you have:

- * idiopathic angioedema
- * hereditary angioedema.

In idiopathic angioedema; swelling of the face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing, can occur for no apparent reason. People with hereditary angioedema are born with this condition.

Do not take Zedace if you are pregnant or plan to become pregnant.

Zedace is not recommended for use in pregnancy as it may affect your developing baby.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are having dialysis or plan to have surgery.

Tell your doctor if you have had the following medical conditions:

- * kidney problems
- * liver problems
- * ischaemic heart disease (e.g. angina)
- * heart failure
- * cerebrovascular disease, a condition that affects the blood vessels of the brain
- * diabetes
- * systemic lupus erythematosus (SLE), scleroderma or other autoimmune diseases
- * neutropenia, a blood disorder where there is a lack of white blood cells
- * a recent bout of diarrhoea or vomiting, or are dehydrated.

If you have not told your doctor about any of the above, tell him/her before you start taking Zedace.

Taking other medicines

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

Some medicines and Zedace may interfere with each other. These include:

- * other medicines used to treat high blood pressure
- * diuretics (also known as fluid tablets), including spironolactone (Aldactone, Spiractin), triamterene (found in Hydrene), amiloride (e.g. Kaluril, Moduretic)

- * medicines used to treat angina
- * potassium supplements (e.g. Slow-K, Span-k) or potassium-containing salt substitutes
- * non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- * lithium (e.g. Lithicarb), a medicine used to treat mood swings and some types of depression
- * some medicines used for coughs, colds, hayfever, sinus problems.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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 are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Zedace.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

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, lightheadedness 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 been prescribed anti-angina medicine, carry it with you when being physically active.
- * Maintain a healthy weight.
- * Discuss your lifestyle and lifestyle plans with your doctor.
- * For more information and tools to improve your heart health, call Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost).

Know warning signs of heart attack and what to do:

- * Tightness, fullness, pressure, squeezing, heaviness or pain in your chest, neck, jaw, throat, shoulders, arms or back.
- * You may also have difficulty breathing, or have a cold sweat or feel dizzy or light headed or feel like vomiting (or actually vomit).
- * If you have heart attack warning signs that are severe, get worse or last for 10 minutes even if they are mild, call triple zero (000). Every minute counts.

Side effects

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

This medicine helps most people, but it may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

You may not experience any of them.

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

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

- * dizziness, lightheadedness, faintness
- * depression
- * feeling more sleepy than usual
- * frequent sneezing, congestion or a runny nose
- * dry cough
- * feeling sick, diarrhoea, stomach pain
- * change in taste.

Tell your doctor as soon as possible if you notice any of the following:

- * signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- * bleeding or bruising more easily than normal
- * unsteadiness when walking
- * red raised, itchy skin rash with or without fever or joint pain
- * yellowing of the skin and/or eyes (jaundice)
- * symptoms of a high blood potassium level, such as:
 - 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
- * passing little or no urine.

The above list includes serious side effects which may require medical attention.

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.

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

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

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 degrees 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)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

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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