

Consumer Medicine Information

What is in this leaflet?

Please read all of this leaflet carefully before you start taking this medicine.

This leaflet answers some common questions about Zonegran capsules. 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 Zonegran capsules 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 are Zonegran capsules used for?

The name of your medicine is Zonegran. The active ingredient in Zonegran capsules is called zonisamide.

Zonegran is used to treat certain types of epilepsy in adults. Zonegran may be used:

- On its own to treat seizures in adults.
- With other antiepileptic medicines to treat seizures in adults.

Epilepsy is caused by a disruption in the electrical activity of the brain. The abnormal electrical impulses occur due to altered levels of some chemicals in the brain. Zonegran can control brain chemicals which send signals to nerves so that seizures do not happen.

Zonegran is used in partial seizures that affect only one part of the brain, with or without generalized seizures that may affect the whole brain.

Your doctor may have prescribed Zonegran capsules for another use. Ask your doctor if you have any questions about why Zonegran capsules has been prescribed for you.

There is no evidence that Zonegran is addictive.

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

Zonegran capsules is not recommended for children under 18 years of age as there is not enough information on its use in children and adolescents.

Before you take Zonegran capsules

Do not take if:

You must not take Zonegran capsules if you have an allergy to:

- Zonisamide
- Sulphonamide drugs including furosemide (Lasix) and bumetanide (Burinex) (diuretic medicines)
- Any of the ingredients listed at the end of this leaflet (See "Ingredients")

Symptoms of an allergic reaction to Zonegran capsules may include:

- Shortness of breath, wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body
- Skin rash, itching or hives.

Zonegran capsules must not be given to anyone who is unconscious or in a coma.

Do not take Zonegran capsules after the expiry date (EXP) printed on the package.

Do not take Zonegran capsules if the packaging is damaged or shows signs of tampering. Do not take Zonegran capsules which have not been properly stored.

If the pack of Zonegran capsules has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking Zonegran capsules, talk to your doctor or pharmacist.

Tell your doctor if:

You must tell your doctor if:

- You have had an allergic reaction to similar medicines (ask your doctor to check your records).
- You are allergic to any other substances such as food preservatives or dyes (Zonegran 100mg capsules contain a yellow colour called sunset yellow FCF (E110) which may cause allergic reactions).
- You are pregnant or intend to become pregnant.
Like most antiepileptic medicines, Zonegran is not recommended for use during pregnancy. Your doctor will discuss with you the possible risks and benefits of using Zonegran capsules during pregnancy.
- You are breast feeding, or wish to breast feed.
It is recommended that you do not breast feed while taking Zonegran capsules. This medicine may pass into the breast milk and there is a possibility that your baby may be affected. Your doctor will discuss with you the possible risks and benefits of using Zonegran capsules during breast feeding.
- You have any of the following medical conditions: liver or kidney disease or kidney stones.
- You have a reduced white blood cell count or have recently lost weight (or weigh less than 40kg).

Taking other medicines:

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

Some medicines may affect the way other medicines work. They may also react with Zonegran capsules resulting in untoward or sometimes dangerous side effects. Your doctor or pharmacist will be able to tell you which medicines are safe to take with Zonegran capsules.

Some other antiepileptic drugs such as phenytoin, carbamazepine and phenobarbitone may affect Zonegran, so tell your doctor if you are taking these drugs.

Your doctor or pharmacist will have more information on medicines that you need to be careful with or need to avoid while taking Zonegran capsules.

Before you start to take any other medicines, tell your doctor or pharmacist that you are taking Zonegran capsules.

How do I take Zonegran capsules?

Follow your doctor's instructions about how to take Zonegran capsules.

Read the directions label of your Zonegran capsules carefully. If you have any concerns about how to take Zonegran capsules, talk to your doctor or pharmacist.

How much to take:

When you take Zonegran on its own:

The usual starting dose is 100mg daily taken once a day. This may be increased by up to 100mg at intervals of two weeks. The usual daily dose is 300mg once a day.

When you take Zonegran with other antiepileptic medicines:

The usual starting dose is 50mg daily taken in two divided doses. The dose will be gradually increased at intervals of one or two weeks, to a daily dose of between 300mg and 500mg per day. Some patients respond to lower doses.

If you have a kidney problem your doctor may start you on a lower dose and increase it more gradually to prevent unwanted side effects.

Your doctor or pharmacist will tell you how much Zonegran capsules you will need to take each day.

How to take it:

Take your capsules at about the same time each day. Zonegran capsules may need to be taken once or twice a day. Taking Zonegran capsules at the same time each day will help you to remember when to take it.

Zonegran capsules must be swallowed whole with water. Do not chew the capsules.

Zonegran can be taken with or without food.

How long to take it for:

Keep taking your Zonegran capsules for as long as your doctor tells you.

Zonegran capsules help to control your condition, but does not cure it. Therefore, it is important that you keep taking Zonegran capsules every day. Your doctor will check your progress to make sure the medicine is working and will discuss with you how long your treatment should continue.

Zonegran is meant to be taken as a long-term medicine. Do not reduce your dose or stop your medicine unless your doctor tells you to.

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 it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not try and make up for the dose that you missed by taking more than one dose at a time. 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 medicine, ask your pharmacist for some hints.

What do I do if I 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 your nearest hospital, if you think that you or anyone else may have taken too much Zonegran. Do this, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

Keep telephone numbers for these places handy.

Signs of overdose include drowsiness and sleepiness. You should not drive at this time.

While you are taking Zonegran capsules

Things you must do:

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

Tell your doctor immediately if you become pregnant while taking Zonegran capsules.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Zonegran capsules.

If you are about to start taking any new medicines, remind your doctor, dentist or pharmacist that you are taking Zonegran capsules.

Your doctor will check your progress and may want to take some blood tests from time to time. This helps to prevent unwanted side effects.

Persons taking Zonegran capsules may be more likely to think about killing themselves or actually trying to do so, especially when Zonegran capsules are first started or the dose is changed. Tell your doctor immediately if you have thoughts about killing yourself or if you are close to or care for someone using Zonegran capsules who talks about or shows signs of wanting to kill him or herself.

If you or someone you know demonstrates any of the following warning signs of suicide-related behavior while taking Zonegran capsules, contact a healthcare provider immediately, or even go to the nearest hospital for treatment:

- Thoughts or talk of death or suicide
- Thoughts or talk of self-harm or harm to others
- Any recent attempts of self-harm
- New or worse depression
- New or worse anxiety
- Panic attacks
- Trouble sleeping (insomnia)
- Increase in aggressive behaviour, irritability or agitation
- Acting on dangerous impulses
- Extreme increase in activity and talking (mania)
- Other unusual changes in behaviour or mood.

Things you must not do:

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Zonegran capsules to treat any other complaints unless your doctor says to.

Do not stop taking Zonegran capsules, or lower the dosage, even if you are feeling better, without checking with your doctor.

If you stop taking Zonegran capsules suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase. To prevent this, your doctor may gradually reduce the amount of Zonegran capsules you take each day before stopping the medicine completely.

Things to be careful of:

Be careful driving or operating machinery until you know how Zonegran capsules affect you.

As with other antiepileptic medicines, Zonegran capsules may cause drowsiness in some people. Make sure you know how you react to Zonegran capsules before you drive a car, operate machinery, or do anything else that could be dangerous.

Make sure you keep cool in hot weather and drink plenty of water. This will help reduce the risk of kidney stones.

What are the side effects?

The most serious side effects that can occur with Zonegran are:

- Serious skin rash and allergic reactions, which very rarely can cause death.
- Less sweating and increase in your body temperature (fever).
- Suicidal thoughts or actions in some people.
- Increased level of acid in your blood (metabolic acidosis). If left untreated, metabolic acidosis can cause brittle or soft bones (osteoporosis, osteomalacia, osteopenia), kidney stones and can slow the rate of growth in children. Your doctor should do a blood test to measure the level of acid in your blood before and during your treatment with ZONEGRAN.
- Problems with your concentration, attention, memory, thinking, speech, or language.
- Blood cell changes such as reduced red and white blood cell counts that may cause infections or a bleeding tendency.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Zonegran capsules, even if the problem is not listed below.

Like other medicines, Zonegran capsules can sometimes cause unwanted side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. If you get any unwanted side effects, tell your doctor or pharmacist.

MILD EFFECTS

Tell your doctor if you notice any of the following that are troublesome or ongoing, and they worry you:

- drowsiness or sedation (especially early on in the treatment)
- loss of appetite
- loss of weight
- dizziness
- loss of concentration
- nausea
- agitation or irritability
- double vision
- depression
- poor muscle coordination
- confusion
- poor memory

- stomach pains
- diarrhoea
- speech abnormalities
- skin rashes, fever and allergic reactions
- anxiety
- nervousness
- tremor
- sounds in one ear or both ears
- constipation
- dry mouth
- changes in taste
- joint pain
- flu syndrome
- headaches
- shortness of breath

These are more common side effects of Zonegran capsules. They are usually mild and in some cases shortlived.

MORE SERIOUS EFFECTS

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- Sudden signs of allergy such as:
 - a rash, itching or hives on the skin
 - swelling of the face, lips, tongue or other parts of the body
 - wheezing or troubled breathing
- Thoughts about suicide or dying
- Attempt to commit suicide
- New or worse depression
- New or worse anxiety
- Feeling agitated or restless
- Panic attacks
- Trouble sleeping (insomnia)
- New or worse irritability
- Acting aggressive, being angry, or violent
- Acting on dangerous impulses
- An extreme increase in activity and talking (mania)
- Other unusual changes in behaviour or mood
- Fever
- Sore throat or sores in your mouth
- Unusual bruising
- Signs of increased acid level in the blood:
 - headaches
 - drowsiness
 - shortness of breath
 - loss of appetite
- Sharp abdominal pain (kidney or urinary stones)
- Muscle pain or weakness
- Loss of balance or difficulty walking
- Seizure or convulsion

These are very serious side effects. You may need urgent medical attention or hospitalisation. Life threatening reactions can include coma and even death. These side effects are rare.

OTHER EFFECTS

There are also some side effects which you may not see. These include:

- changes in blood chemistry
- inflammation of the pancreas
- liver problems
- kidney problems
- decrease in white blood cells
- reduction in bone volume

Please note that during your treatment with Zonegran capsules, your doctor may from time to time test your blood to look for any side effects which the medication could cause. Your doctor or pharmacist will have more information. Your doctor or pharmacist should discuss the possible side effects of Zonegran capsules with you.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

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

How do I store Zonegran capsules?

Storage:

Zonegran capsules should be stored in a safe place where children cannot reach them.

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

Keep your Zonegran capsules in its packaging until it is time to take it.

Zonegran capsules should be stored below 25°C and kept away from light.

Do not leave Zonegran capsules in the car or on windowsills. Do not store medicines in the bathroom or near a sink. Heat and dampness can destroy some medicines.

Disposal:

If your doctor tells you to stop taking Zonegran capsules, ask your pharmacist what to do with any capsules that are left over.

Product Description

What it looks like:

- **Zonegran capsules 25mg:** a white opaque capsule body with a white opaque cap, printed with a logo and "ZONEGRAN 25" in black print.
- **Zonegran capsules 50mg:** a white opaque capsule body with a grey opaque cap, printed with a logo and "ZONEGRAN 50" in black print.
- **Zonegran capsules 100mg:** a white opaque capsule body with a red opaque cap, printed with a logo and "ZONEGRAN 100" in black print.

Ingredients:

Zonegran capsules 25mg

Active Ingredients: Zonisamide

Inactive Ingredients:

- microcrystalline cellulose
- hydrogenated vegetable oil
- sodium laurylsulphate

Capsule shell:

- gelatin
- titanium dioxide (E171)

Post-printing ink:

- black iron oxide (E172)
- shellac
- propylene glycol
- potassium hydroxide

Zonegran capsules 50mg

Active Ingredients: Zonisamide

Inactive Ingredients:

- microcrystalline cellulose
- hydrogenated vegetable oil
- sodium laurylsulphate

Capsule shell:

- gelatin
- titanium dioxide (E171)
- black iron oxide (E172)

Post-printing ink:

- black iron oxide (E172)
- shellac
- propylene glycol
- potassium hydroxide

Zonegran capsules 100mg

Active Ingredients: Zonisamide

Inactive Ingredients:

- microcrystalline cellulose
- hydrogenated vegetable oil
- sodium laurylsulphate

Capsule shell:

- gelatin
- titanium dioxide (E171)
- allura red AC (E129)
- sunset yellow FCF (E110)

Post-printing ink:

- black iron oxide (E172)
- shellac
- propylene glycol
- potassium hydroxide

Where to go to for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice.

Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Sponsor

Zonegran is supplied in Australia by:

SciGen (Australia) Pty Ltd

Suite 1, 13b Narabang Way

Belrose NSW 2085

Australia

Telephone: 1800 966 303



Australian Registration Number

Zonegran capsules 25mg: AUST R 125869

Zonegran capsules 50mg: AUST R 125870

Zonegran capsules 100mg: AUST R 125871

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