

## Consumer Medicine Information (CMI) summary

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

### 1. Why am I using Zonegran?

Zonegran contains the active ingredient Zonisamide. Zonegran is used to treat certain types of epilepsy in adults

For more information, see Section [1. Why am I using Zonegran](#) in the full CMI.

### 2. What should I know before I use Zonegran?

Do not use if you have ever had an allergic reaction to Zonisamide 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 use Zonegran?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Zonegran 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 use Zonegran?

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

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

### 5. What should I know while using Zonegran?

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|------------------------------------|---|
| <b>Things you should do</b>        | <ul style="list-style-type: none"><li>• Tell your doctor if, for any reason, you have not taken your medicine exactly as directed. If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Zonegran.</li><li>• Tell any other doctors, dentists and pharmacists who treat you that you are taking Zonegran.</li><li>• If you become pregnant while taking Zonegran, tell your doctor immediately.</li></ul> |
| <b>Things you should not do</b>    | <ul style="list-style-type: none"><li>• Do not use Zonegran to treat any other complaints unless your doctor tells you to. Do not give your medicine to anyone else, even if their symptoms seem similar to yours.</li><li>• Do not stop taking your medicine or lower the dosage, even if you are feeling better, without checking with your doctor.</li></ul>   |
| <b>Driving or using machines</b>   | <ul style="list-style-type: none"><li>• Do not drive or operating machinery until you know how Zonegran affects you.</li></ul>  |
| <b>Looking after your medicine</b> | <ul style="list-style-type: none"><li>• Keep your medicine in a cool dry place away from light and where the temperature stays below 25°C</li></ul>   |

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

### 6. Are there any side effects?

Common side effects include agitation, irritability, confusion, depression, poor muscle coordination, dizziness, poor memory, sleepiness, double vision, loss of appetite, decreased blood levels of bicarbonate. Serious side effects include difficulty breathing, a swollen face, lips or tongue, or a severe skin rash as these symptoms may indicate that you are having a severe allergic reaction, have signs of overheating - high body temperature but little or no sweating, rapid heartbeat and breathing, muscle cramps, and confusion, have thoughts of harming or killing yourself. A small number of people being treated with antiepileptics such as Zonegran have had thoughts of harming or killing themselves.

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.

# Zonegran® (zon-is-a-mide)

Active ingredient(s): Zonisamide

## Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

### 1. Why am I using Zonegran

Zonegran contains the active ingredient 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.

### 2. What should I know before I use Zonegran?

#### Warnings

Do not use Zonegran if:

- you are allergic to Zonisamide or any of the ingredients listed at the end of this leaflet.

Sulphonamide drugs including furosemide (Lasix) and bumetanide (Burinex) (diuretic medicines) Some of the symptoms of an allergic reaction may include:

- shortness of breath;
- wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin

Check with your doctor if you:

- You have had an allergic reaction to similar medicines (ask your doctor to check your records) Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop Some other antiepileptic drugs such as phenytoin, carbamazepine and phenobarbitone may affect Zonegran, so tell your doctor if you are taking these drugs. You have liver or kidney disease or kidney stones.
- You have a reduced white blood cell count or have recently lost weight (or weigh less than 40 kg).
- You have high blood levels of ammonia

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

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..

It is recommended that you do not breastfeed while taking or for one month after stopping 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 breastfeeding. [Include any other relevant pregnancy information specific to the medicine].

**Do not give this medicines to anyone who is unconscious or in a coma.**

- Do not give this medicine to anyone under the age of 18 years. Zonegran capsules is not recommended for children and adolescents under 18 years of age as there is not enough information on its use in children and adolescents. Safety and effectiveness in children younger than 18 years have not been established.

### 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 Zonegran and affect how it works.**

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.

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

## 4. How do I use Zonegran

### How much to take / use

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

### When to take / use Zonegran

- Zonegran should be used at the same time each day will have the best effect. It will also help you remember when to take it.

### How long to take Zonegran

- Continue taking your medicine for as long as your doctor tells you. Do not stop unless your doctor advises you to.
- 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 have any further questions on the use of this medicine, ask your doctor or pharmacist.

### If you forget to use Zonegran

Zonegran should be used regularly at the same time each day

**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 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 medicine, ask your pharmacist for some hints.

### If you use too much Zonegran

If you think that you have used too much Zonegran you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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 using Zonegran?

### Things you should 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.

#### Call your doctor straight away if you:

- are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Zonegran
- become pregnant while taking Zonegran, tell your doctor immediately. Do not stop treatment without first discussing it with your doctor. You must only take zonisamide during your pregnancy if your doctor tells you to. If you are a woman of childbearing age you must use adequate contraception while taking zonisamide and for one month after stopping zonisamide.
- 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.
  - 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.
- If you or someone you know demonstrates any of the following warning signs of suicide-related behaviour 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 selfharm or harm to others
  - Any recent attempts of selfharm
  - 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.
- Make sure you keep cool in hot weather and drink plenty of water. This will help reduce the risk of kidney stones.

Remind any doctor, dentist or pharmacist you visit that you are using Zonegran.

### Things you should not do

- Do not use Zonegran to treat any other complaints unless your doctor tells you to Do not give your medicine to anyone else, even if their symptoms seem similar to yours.
- Do not stop taking your medicine 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.

### Driving or using machines

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

### Looking after your medicine

- Keep your medicine in the original container If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place away from light and where the temperature stays below 25°C. 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**

### When to discard your medicine

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. **Getting rid of any unwanted medicine**

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

Do not use 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.

### Less serious side effects

Less serious side effects	What to do
<p><b>Very common side effects (may affect more than 1 in 10 people) are:</b></p> <ul style="list-style-type: none"> <li>• agitation, irritability confusion, depression poor muscle coordination, dizziness, poor memory, sleepiness, double vision</li> <li>• loss of appetite, decreased blood levels of bicarbonate (a substance that prevents your blood from becoming acidic)</li> </ul> <p><b>Common side effects (may affect up to 1 in 10 people) are:</b></p> <ul style="list-style-type: none"> <li>• difficulty sleeping, strange or unusual thoughts, feeling anxious or emotional.</li> <li>• slowed thoughts, loss of concentration, speech abnormalities, abnormal skin sensation (pins and needles), tremor, involuntary movement of the eyes.</li> <li>• kidney stones.</li> <li>• skin rashes, itching, allergic reactions, fever, tiredness, flu-like symptoms, hair loss.</li> <li>• ecchymosis (a small bruise caused by blood leaking from broken blood vessels in the skin).</li> <li>• loss of weight, nausea, indigestion, stomach pains, diarrhoea (loose stools), constipation.</li> <li>• swelling of the feet and legs.</li> </ul> <p><b>Uncommon side effects (may affect up to 1 in 100 people) are:</b></p> <ul style="list-style-type: none"> <li>• anger, aggression, thoughts of suicide, suicide attempt.</li> <li>• vomiting.</li> <li>• gall bladder inflammation, gallstones.</li> <li>• urinary stones.</li> <li>• lung infection / inflammation, urinary tract infections.</li> <li>• low blood potassium levels, convulsions/seizures.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<p><b>Very rare side effects (may affect up to 1 in 10,000 people) are:</b></p> <ul style="list-style-type: none"> <li>• hallucinations, memory loss, coma, neuroleptic malignant syndrome (inability to move, sweating, fever, incontinence), status epilepticus (prolonged or repeated seizures).</li> <li>• breathing disorders, shortness of breath, inflammation of the lungs.</li> <li>• inflammations of the pancreas (severe pain in the stomach or back)</li> <li>• liver problems, kidney failure, increased blood levels of creatinine (a waste product that your kidneys should normally remove).</li> <li>• severe rashes or skin peeling (at the same time you may feel unwell or develop a fever).</li> <li>• abnormal muscle breakdown (you may feel pain or weakness in your muscles) which can lead to kidney problems.</li> <li>• swollen glands, blood disorders (reduction in the number of blood cells, which can make infection more likely and can make you look pale, feel tired and feverish, and bruise more easily).</li> <li>• decreased sweating, overheating.</li> <li>• glaucoma, which is a blockage of fluid in the eye causing increased pressure in the eye. Eye pain, blurred vision or decreased vision may occur and can be signs of glaucoma.</li> <li>• high blood ammonia levels which can affect your mental activities, slow your alertness, make you feel tired, or cause vomiting.</li> </ul>	
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<p>thoughts of harming or killing themselves.</p> <ul style="list-style-type: none"> <li>• have pain in your muscles or a feeling of weakness, as this may be a sign of abnormal muscle breakdown which can lead to kidney problems.</li> <li>• get a sudden pain in your back or stomach, have pain on urinating (passing water) or notice blood in your urine, as this may be a sign of kidney stones. develop visual problems such as eye pain or blurred vision while taking Zonegran.</li> </ul> <p><b>Contact your doctor as soon as possible if you:</b></p> <ul style="list-style-type: none"> <li>• have an unexplained skin rash, as this could develop into a more severe skin rash or skin peeling.</li> <li>• feel unusually tired or feverish, have a sore throat, swollen glands, or find that you bruise more easily, as this may mean you have a blood disorder.</li> <li>• have signs of increased acid level in the blood- headaches, drowsiness, shortness of breath</li> <li>• have signs of high blood ammonia levels. High ammonia in the blood can affect your mental activities, slow your alertness,</li> <li>• make you feel tired, or cause vomiting, and</li> <li>• loss of appetite. Your doctor may need to monitor or treat this.</li> </ul>	
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

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.

### 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](http://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.**

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• <b>Contact your doctor immediately if you:</b> have difficulty breathing, a swollen face, lips or tongue, or a severe skin rash as these symptoms may indicate that you are having a severe allergic reaction.</li> <li>• have signs of overheating - high body temperature but little or no sweating, rapid heartbeat and breathing, muscle cramps, and confusion.</li> <li>• have thoughts of harming or killing yourself. A small number of people being treated with antiepileptics such as Zonegran have had</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

## 7. Product details

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

### What Zonegran capsules 25mg contains

<b>Active ingredient (main ingredient)</b>	Zonisamide
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• microcrystalline cellulose</li><li>• hydrogenated vegetable oil</li><li>• sodium laurylsulphate</li></ul>
<b>Capsule shell</b>	<ul style="list-style-type: none"><li>• gelatin</li><li>• titanium dioxide (E171)</li><li>• TekPrint SW-9008 Black Ink (ARTG No 2328)</li></ul>

### What Zonegran capsules 50mg contains

<b>Active ingredient (main ingredient)</b>	Zonisamide
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• microcrystalline cellulose</li><li>• hydrogenated vegetable oil</li><li>• sodium laurylsulphate</li></ul>
<b>Capsule shell</b>	<ul style="list-style-type: none"><li>• gelatin</li><li>• titanium dioxide (E171)</li><li>• black iron oxide (E172)</li><li>• TekPrint SW-9008 Black Ink (ARTG No 2328)</li></ul>

### What Zonegran capsules 100mg contains

<b>Active ingredient (main ingredient)</b>	Zonisamide
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• microcrystalline cellulose</li><li>• hydrogenated vegetable oil</li><li>• sodium laurylsulphate</li></ul>
<b>Capsule shell</b>	<ul style="list-style-type: none"><li>• gelatin</li><li>• titanium dioxide (E171)</li><li>• allura red AC (E129)</li><li>• sunset yellow FCF (E110)</li><li>• TekPrint SW-9008 Black Ink (ARTG No 2328)</li></ul>

**This medicine does not contain gluten, tartrazine or any other azo dyes.**

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

## What Zonegran looks like

Zonegran capsules 25mg: a white opaque body and a white opaque cap and printed with "ZONEGRAN 25" in black on the capsule body. Capsule size No 4 containing white powder free from visible impurities.

Australian Registration Number: AUST R 125869

Zonegran capsules 50mg: a white opaque body and a grey opaque cap and printed with "ZONEGRAN 50" in black on the capsule body. Capsule Size No 3 containing white powder free from visible impurities.

Australian Registration Number: AUST R 125870

Zonegran capsules 100mg: a white opaque body and a red opaque cap and printed with "ZONEGRAN 100" in black on the capsule body. Capsule size No 1 containing white powder free from visible impurities.

Australian Registration Number: AUST R 125871

## Who distributes Zonegran

Amdipharm Mercury (Australia) Pty Ltd

Level 9, 76 Berry Street

North Sydney NSW 2060

Ph: 1800 627 680

This leaflet was prepared in November 2025