

# Zonisamide Te Arai

## **Zonisamide**

Zonisamide 25 mg hard capsules  
Zonisamide 50 mg hard capsules  
Zonisamide 100 mg hard capsules

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## **What is in this leaflet**

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Please read this leaflet carefully before you start using Zonisamide Te Arai.

This leaflet answers some common questions about Zonisamide Te Arai. 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 using Zonisamide Te Arai against the benefits they expect it will have for you.

**If you have any concerns about using this medicine, ask your doctor or pharmacist.**

Keep this leaflet with the medicine. You may need to read it again.

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## **What Zonisamide Te Arai is used for**

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Zonisamide Te Arai contains the active substance zonisamide, and is used as an antiepileptic medicine. Zonisamide is used to treat seizures that affect one part of the brain (partial seizure), which may or may not be followed by a seizure affecting all of the brain (secondary generalisation).

Zonisamide may be used:

- On its own to treat seizures in adults.
- With other antiepileptic medicines to treat seizures in adults, adolescents, and children aged 6 years and above.

Your doctor may have prescribed zonisamide for another reason.

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

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

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## Before you use Zonisamide Te Arai

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### ***When you must not use it***

Do not use zonisamide if you:

- are allergic to zonisamide or any of the other ingredients of this medicine (listed in the Product Description section below.),
- are allergic to other sulphonamide medicines. Examples include: sulphonamide antibiotics, thiazide diuretics, and sulfonylurea anti-diabetes medicines.

If you are not sure whether you should start using zonisamide, talk to your doctor.

### ***Before you start to use it***

Zonisamide belongs to a group of medicines (sulphonamides) which can cause severe allergic reactions, severe skin rashes, and blood disorders, which very rarely can be fatal.

### **Serious rashes occur in association with zonisamide therapy, including cases of Stevens-Johnson syndrome.**

Tell your doctor if you:

- are younger than 12 years old, as you may be at greater risk of decreased sweating, heat stroke, pneumonia and liver problems. If you are younger than 6 years old, zonisamide is not recommended for you.
- are elderly, as your dose of zonisamide may need adjusting, and you may be more likely to develop an allergic reaction, severe skin rash, swelling of the feet and legs, and itchiness when taking zonisamide.
- suffer from liver problems, as your dose of zonisamide may need adjusting.
- have eye problems such as glaucoma.
- suffer from kidney problems as your dose of zonisamide may need adjusting.
- have previously suffered from kidney stones, as you may be at increased risk of developing more kidney stones. **Reduce the risk of kidney stones by drinking sufficient water.**

- live in a place or are on holiday in a place where the weather is warm. Zonisamide can make you perspire less, which can cause your body temperature to increase. **Reduce the risk of overheating by drinking sufficient water and keeping cool.**
- are underweight, or have lost a lot of weight as zonisamide can cause you to lose more weight. Tell your doctor as this may need to be monitored.
- are pregnant or could become.

If you have not told your doctor about any of the above, tell them before you start using zonisamide.

### **Children and Adolescents**

Talk to your doctor about the following risks:

#### Preventing overheating and dehydration in children

Zonisamide can cause your child to sweat less and overheat and if your child is not treated this can lead to brain damage and death. Children are most at risk especially in hot weather.

When your child is taking zonisamide

- Keep your child cool especially in hot weather
- Your child must avoid heavy exercise especially when the weather is hot
- Give your child plenty of cold water to drink
- Your child must not take these medicines:  
carbonic anhydrase inhibitors (like topiramate and acetazolamide), and anticholinergic agents (like clomipramine, hydroxyzine, diphenhydramine, haloperidol, imipramine and oxybutynin).

If your child's skin feels very hot with little or no sweating, becomes confused, has muscle cramps, or your child's heartbeat or breathing becomes rapid:

- Take your child to a cool, shaded place
- Sponge your child's skin with cool (not cold) water
- Give your child cold water to drink
- Seek urgent medical assistance.

- Body weight: You should monitor your child's weight every month and see your doctor as soon as possible if your child is not gaining enough weight. Zonisamide is not recommended for children who are underweight or have a small appetite, and should be used with caution in those below 20 kg.
- Increased acid level in the blood and kidney stones: Reduce these risks by ensuring that your child drinks enough water and is not taking any other medicine which could cause kidney stones (see Other medicines). Your doctor will monitor your child's blood bicarbonate levels and kidneys (see Side Effects section below).

Do not give this medicine to children below the age of 6 years because it is not known for this age group whether the potential benefits are greater than the risks.

### ***Taking other medicines***





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## **While you are using Zonisamide Te Arai**

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### ***Things you must do***

If you are a woman of childbearing age you must use adequate contraception while taking and for one month after stopping zonisamide.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You should not stop your treatment without discussing this with your doctor.

You must only take zonisamide during your pregnancy if your doctor tells you to. Research has shown an increased risk of birth defects in children of women taking anti-epileptic medicines. A study showed that babies born to mothers using zonisamide during pregnancy were smaller than expected for their age at the birth, compared with babies born to mothers treated with lamotrigine monotherapy. Make sure you are fully informed about the risks and the benefits of using zonisamide for epilepsy during pregnancy.

Do not breastfeed whilst taking, or for one month after stopping zonisamide

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking zonisamide.

### ***Things you must not do***

Do not give Zonisamide to anyone else, even if they have the same condition as you.

### ***Things to be careful of***

Zonisamide may affect your concentration, ability to react/respond, and may make you feel sleepy, particularly at the beginning of your treatment or after your dose is increased. Be especially careful while driving or operating machinery, if zonisamide you in this way.

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## **In case of overdose**

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### ***If you take too much (overdose)***

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much zonisamide.

You may become sleepy and could lose consciousness. You might also feel sick, have a sore stomach, muscle twitches, eye movement, feel faint, have a slowed heart beat, and reduced breathing and kidney function. Do not try to drive.

Do this even if there are no signs of discomfort or poisoning.

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## Side Effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

Zonisamide belongs to a group of medicines (sulphonamides) that can cause severe allergic reactions, severe skin rashes, and blood disorders, which very rarely can be fatal.

### **Contact your doctor immediately if you:**

- 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.
- 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 anti- epileptics such as zonisamide have had thoughts of harming or killing themselves.
- 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.
- 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 zonisamide.

### **Contact your doctor as soon as possible if you:**

- have an unexplained skin rash, as this could develop into a more severe skin rash or skin peeling.
- 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.
- have signs of increased acid level in the blood- headaches, drowsiness, shortness of breath and loss of appetite. Your doctor may need to monitor or treat this.

Your doctor may decide that you should stop using zonisamide.





Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

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## Product description

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### ***What it looks like***

Zonisamide Te Arai 25 mg hard capsules are hard gelatin capsules with white opaque cap and white opaque body (size 4, 14.4 mm  $\pm$  0.4 mm) filled with white to off white granules.

Zonisamide Te Arai 50 mg hard capsules are hard gelatin capsules with grey opaque cap and white opaque body (size 3, 15.8 mm  $\pm$  0.4 mm) filled with white to off white granules.

Zonisamide Te Arai 100 mg hard capsules are hard gelatin capsules with red opaque cap and white opaque body (size 1, 19.3 mm  $\pm$  0.4 mm) filled with white to off white granules.

### ***Ingredients***

#### Active ingredient(s):

- Zonisamide Te Arai 25 mg hard capsules contain 25 mg of zonisamide.
- Zonisamide Te Arai 50 mg hard capsules contain 50 mg zonisamide.
- Zonisamide Te Arai 100 mg hard capsules contain 100 mg zonisamide.

#### Inactive ingredients:

The other ingredients that are present in the capsule contents are: cellulose, microcrystalline, hydrogenated vegetable oil and macroglycerol hydroxystearate.

The capsule shell contains:

*Zonisamide Te Arai 25 mg hard capsules*  
Gelatin and titanium dioxide (E171)

*Zonisamide Te Arai 50 mg hard capsules*  
Gelatin, titanium dioxide (E171) and iron oxide black (E172)

*Zonisamide Te Arai 100 mg hard capsules*  
Gelatin, titanium dioxide (E171), Ponceau 4 R (E124) and quinolone yellow (E104)

**Zonisamide Te Arai contains Macroglycerol hydroxystearate**

Macrogolglycerol hydroxystearate may cause stomach upset and diarrhoea.

**Zonisamide Te Arai 100 mg contains Ponceau 4 R (E124)**

Ponceau 4 R (E124) may cause allergic reactions.

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## **Sponsor Details**

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Zonisamide Te Arai is supplied in New Zealand by:

Te Arai BioFarma Ltd

PO Box 46205  
Herne Bay  
Auckland, 1147  
NEW ZEALAND

0800 832 724

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## **Date of Preparation**

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This leaflet was prepared on 27 June 2022.