Zarontin

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> 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 Zarontin?

Zarontin contains the active ingredient ethosuximide. Zarontin is used to control epilepsy in children and children. Zarontin is used to control petit mal seizures. For more information, see Section <u>1. Why am I using</u> <u>Zarontin?</u> in the full CMI.

2. What should I know before I use Zarontin?

Do not use if you have ever had an allergic reaction to Zarontin, succinimides or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any other allergies, 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 Zarontin? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Zarontin and affect how it works. A list of these medicines is in Section <u>3.</u> <u>What if I am taking other medicines?</u> in the full CMI.

4. How do I use Zarontin?

- Swallow Zarontin capsules while with a full glass of water.
- For Zarontin syrup, shake the bottle well and accurately pour the dose with a medicine measure before taking it.

More instructions can be found in Section <u>4. How do I</u> <u>use Zarontin?</u> in the full CMI.

5. What should I know while using Zarontin?	
Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Zarontin. Tell your doctor immediately if you are having thoughts about suicide or self-harm.

	 If you become pregnant while taking Zarontin, tell you doctor. If you are breastfeeding, watch your baby carefully.
Things you should not do	 Do not stop using this medicine unless your doctor tells you to. Do not give Zarontin to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.
Driving or using machines	 Zarontin may cause dizziness, light- headedness, tiredness, drowsiness and affect alertness. Make sure you know how you react to Zarontin before you drive a car, operate machinery, or do anything else that could be dangerous if you are affected.
Drinking alcohol	 Drinking alcohol when taking Zarontin can

	make you more sleepy, dizzy or lightheaded.
Looking after your medicine	 Keep your capsules or syrup in a cool dry place where the temperature stays below 25°C. Keep it where children cannot reach it.

For more information, see Section <u>5. What should I know</u> while using Zarontin? in the full CMI.

6. Are there any side effects?

Speak to your doctor or pharmacist if you have any less serious side effects and they worry you. Tell your doctor as soon as possible if you: have thoughts of suicide or self-harm, notice unusual changes in mood or show signs of depression. 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: more frequent or severe seizures, severe depression, apparent intentions of suicide, aggressive behaviour, frequent infections, frequent nosebleeds, persistent nausea or vomiting, sudden signs of allergy, severe skin rash. For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

Zarontin

Active ingredient(s): ethosuximide

Consumer Medicine Information (CMI)

This leaflet provides important information about using Zarontin. 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 Zarontin.

Where to find information in this leaflet:

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

1. Why am I using Zarontin?

Zarontin contains the active ingredient

ethosuximide. Zarontin belongs to a group of medicines called anticonvulsants. These drugs are thought to work by controlling brain chemicals which send signals to nerves so that seizures (fits) do not happen.

Zarontin is used to control epilepsy in children and adults. Epilepsy is a condition where you have repeated seizures. There are many different types of seizures, ranging from mild to severe.

Zarontin is used to control petit mal seizures.

Zarontin may be used alone, or in combination with other medicines, to treat your condition.

Your doctor may have prescribed Zarontin for another reason. Ask your doctor if you have any questions about why Zarontin has been prescribed for you.

There is no evidence that Zarontin is addictive.

2. What should I know before I use Zarontin?

Warnings

Do not use Zarontin if:

- you have an allergy to ethosuximide, other medicines which contain succinimides or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Symptoms of an allergic reaction to Zarontin 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:

- have allergies to:
 - any other medicines, especially barbiturates or any other anticonvulsant medicines
 - any other substances, such as foods, preservatives or dyes.
- Have or have had any medical conditions, especially the following:
 - liver problems
 - kidney problems
 - systemic lupus erythematosus
 - frequent infections such as fever, chills, sore throat or mouth ulcers.

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 <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant

If it is necessary for you to take Zarontin your doctor can help you decide whether or not to take it during pregnancy. Zarontin may affect your developing baby if you take it during pregnancy. However, it is very important to control your fits while you are pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed

Your doctor will discuss the possible risks and benefits of taking Zarontin during breastfeeding.

If you do breastfeed, watch your baby carefully.

If your baby develops a skin rash becomes sleepy or has unusual symptoms, do not breastfeed again until you speak to your doctor.

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

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 and Zarontin may interfere with each other. These include other medicines used to treat fits and convulsions, such as phenytoin and valproic acid.

These medicines may be affected by Zarontin, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you. Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Zarontin.

4. How do I use Zarontin?

How much to take

- Your doctor will tell you how much syrup or how many capsules you will need to take each day. This may depend on your age, the severity of your condition and whether or not you are taking any other medicines.
- Your doctor may recommend that you start with a low dose of Zarontin and slowly increase the dose to the lowest amount needed to control your epilepsy/ convulsions.
- Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.
- Use Zarontin until your doctor tells you to stop.
- If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

When to take Zarontin

- Take the daily dose of Zarontin in two divided doses.
- Take Zarontin at about the same time each day.
- Taking Zarontin at the same time each day will have the best effect. It will also help you remember when to take the capsules or syrup.

 It does not matter if you take Zarontin before or after food.

How to take Zarontin

- If you are taking Zarontin capsules: swallow Zarontin capsules whole with a full glass of water.
- If you or your child are taking Zarontin syrup: Shake the bottle well and accurately pour the dose with a medicine measure before taking it.

Shaking the bottle and using a medicine measure will make sure that you get the correct dose. You can get a medicine measure from your pharmacist. Ask your pharmacist for ways to accurately measure the dose.

If you forget to use Zarontin

Zarontin should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your medicine as you would normally.

If it is almost time for your next dose (within 4 hours), skip the dose you missed and take your next dose when you are meant to.

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.

How long to take Zarontin

- Continue taking Zarontin for as long as your doctor tells you to.
- Zarontin helps control your condition but does not cure it. Therefore, you must take your medicine every day, even if you feel well.
- Do not stop taking Zarontin, or lower the dosage, without checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.
- Stopping Zarontin suddenly may cause unwanted effects or make your condition worse. Your doctor will slowly reduce your dose before you can stop taking it completely.

If you use too much Zarontin

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

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 (Australia) or 0800 764 66 (New Zealand)), 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 Zarontin?

Things you should do

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

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used.

If you become pregnant while taking Zarontin, tell your doctor.

Tell your doctor if you are breastfeeding or plan to breastfeed. If you do breastfeed, watch your baby carefully.

Tell your doctor if you feel Zarontin is not helping your condition. Your doctor may need to change your medicine.

Tell your doctor if, for any reason, you have not taken Zarontin exactly as prescribed. Otherwise, your doctor may change your treatment unnecessarily.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

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

Call your doctor straight away if you notice any of the following:

- increase in seizures (fits)
- itchy red skin rash or hives, fever, enlarged lymph glands

These symptoms may mean that you have a severe hypersensitivity reaction to this medicine. You may need urgent medical attention.

 yellowing of the skin and/or eyes, swelling of the face, strong stomach pains, generally feeling unwell with tiredness, weakness and vomiting

These symptoms may mean that you have a serious condition affecting your liver. You may need urgent medical attention.

Suicide, mood and behaviour changes

Tell your doctor immediately if you have any thoughts about suicide or self-harm, any unusual changes in mood or behaviour, or you show signs of depression

Some people being treated with anti-epileptics such as Zarontin have thoughts of harming or killing themselves.

Patients and caregivers should be alert and monitor for these effects.

Signs and symptoms of suicide include:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation
- feelings of depression.

Mention of suicide or violence must be taken seriously.

If you or someone you know is demonstrating these warning signs of suicide while taking Zarontin, contact your doctor or a mental health professional right away.

Things you should not do

- Do not give Zarontin to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.
- Do not take Zarontin to treat any other complaints unless your doctor tells you to.
- Do not stop taking it unless your doctor tells you to.

Driving or using machines

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

Zarontin may cause dizziness, light-headedness, tiredness, drowsiness and affect alertness. Make sure you know how you react to Zarontin before you drive a car, operate machinery, or do anything else that could be dangerous if you are affected.

Children

Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling drowsy or sleepy.

Drinking alcohol

Tell your doctor if you drink alcohol.

Drinking alcohol when taking Zarontin can make you more sleepy, dizzy or lightheaded. Your doctor may advise you to avoid alcohol while you are being treated with Zarontin.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack they will not keep well.

Keep your capsules or syrup in a cool dry place where the temperature stays below 25°C, away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills on hot days.

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.

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?

Zarontin helps most people with epilepsy, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. However, you may need medical treatment if you get some of the side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

If you get any side effects, do not stop taking Zarontin without first talking to your doctor or pharmacist.

Less serious side effects

Less serious side effects	What to do
 dizziness or light- headedness feeling tired or drowsy headache weakness, unsteadiness when walking mood changes such as feelings of extreme happiness, irritability or excitement hiccoughs loss of concentration disturbance of sleep frightening dreams abnormally suspicious thoughts increased libido indigestion, stomach pain or discomfort nausea (feeling sick) or vomiting cramps 	Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
 loss of appetite 	
 loss of weight 	
• diarrhoea	
 swollen gums or tongue 	
 itchy red skin rash or 	
hives	
 excessive hairiness, especially in women 	
 short sightedness 	
 vaginal bleeding 	
 allergic reaction 	
 blood in the urine. 	

Serious side effects

Serious side effects	What to do
 have any thoughts of suicide or self-harm 	Tell your doctor as soon as possible
 notice any unusual changes in your mood or behaviour show signs of depression 	
depression.	
 more frequent or more severe seizures (fits) 	Call your doctor straight away or go straight to the Emergency Department at your

Serious side effects	What to do
 severe depression, apparent intentions of suicide 	nearest hospital if you notice any of these serious side effects.
 aggressive behaviour 	
 frequent infections with fever, chills, sore throat, swollen glands and mouth ulcers 	
 frequent nosebleeds, unusual bleeding or bruising, 	
 tiredness, headache, shortness of breath when exercising, dizziness or pale skin 	
 persistent nausea or vomiting, loss of appetite, generally feeling unwell, fever, itching, yellowing of the skin and/or eyes, dark coloured urine, light coloured bowel motions, 	
pain in the abdomen. These may be signs of a liver problem.	
 sudden signs of allergy such as rash, itching or hives, swelling of the 	

Serious side effects	What to do
 face, lips, wheezing or difficulty breathing severe skin rash, itching, hives, blisters or peeling skin, which may be accompanied by fever, chills, headache, swollen glands, stomach pain or aching joints and muscles 	
 severe whole body skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

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 <u>www.tga.gov.au/reporting-problems</u>. 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.

7. Product details

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

What Zarontin contains

Active ingredient (main ingredient)	Capsules: • Ethosuzimide 250 mg Syrup: • Ethosuzimide 250 mg/5 mL
Other ingredients (inactive ingredients)	Capsules: • macrogol 400 • gelatin • glycerol • sorbitol • vanillin • methyl hydroxybenzoate • propyl hydroxybenzoate • sunset yellow FCF. Syrup: • sodium citrate

	 sodium benzoate saccharin sodium sucrose glycerol imitation raspberry flavour
	 purified water citric acid monohydrate.
Potential allergens	 benzoates saccharin sugars

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

What Zarontin looks like

Zarontin capsules 250 mg are clear orange soft gelatin capsules, available in bottles of 100 and 200 capsules (AUST R 94175)

Zarontin syrup is a clear yellow to pink solution, available in a 200 mL bottle (Aust R 79031).

Who distributes Zarontin

Zarontin is supplied by:

Clinect Pty Ltd 120-132 Atlantic Drive Keysborough VIC 3173 Australia Free Call Australia: 1800 899 005

Free Call New Zealand: 0800 138 803

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