

Zarontin(R)

ethosuximide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Zarontin.

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 or your child taking Zarontin 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 Zarontin is used for

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

Zarontin is used to control petit mal seizures.

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 do not happen.

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.

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

Before you take Zarontin

When you must not take it

Do not take Zarontin if you have an allergy to ethosuximide, the active ingredient in Zarontin, other succinimides or any of the ingredients listed at the end of this leaflet.

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

Do not take Zarontin after the expiry date (EXP) printed on the pack.

Do not take Zarontin 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 Zarontin, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- * any other medicines, especially barbiturates or any other anticonvulsant medicines
- * any other substances, such as foods, preservatives or dyes

Tell your doctor if you 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

Tell 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.

Tell your doctor if you are breast-feeding or plan to breast-feed.

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

If you do breastfeed, watch your baby carefully.

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

If you have not told your doctor or pharmacist about any of the above,

tell them before you start taking Zarontin.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any 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.

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

How to take 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.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist for help.

How to take it

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.

When to take it

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.

If you forget to take it

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.

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 that 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 it

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 take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (in Australia telephone 13 11 26; in New Zealand 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 Zarontin. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Zarontin

Things you must do

Tell your doctor immediately if you notice any of the following:

- * increase in seizures (fits)
- * 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.

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

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Zarontin.

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

Tell your doctor if you are breast-feeding or plan to breast-feed.

If you do breastfeed, watch your baby carefully.

Before you have any surgery or emergency treatment, tell your doctor or dentist that you are taking Zarontin.

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.

Things you must 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 using it unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Zarontin affects you.

As with other anticonvulsant medicines, Zarontin may cause dizziness, light-headedness, tiredness, and drowsiness in some people. 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 dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

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

Zarontin may cause drowsiness, dizziness or sleepiness in some people and affect alertness.

Be careful when drinking alcohol while taking Zarontin.

Combining Zarontin and alcohol can make you more sleepy, dizzy or lightheaded. Your doctor may suggest you avoid alcohol while you are being treated with Zarontin.

Side effects

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

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. 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.

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

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

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

- * 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
- * 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

These are the more common side effects of Zarontin. Mostly these are mild and short-lived.

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

- * more frequent or more severe seizures (fits)
- * severe depression, apparent intentions of suicide
- * 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 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

These are very serious side effects. You may need urgent medical attention or hospitalisation.

All of these side effects are very rare.

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

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

You may not experience any of them.

After using Zarontin

Storage

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 degrees C.

Do not store Zarontin or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

If your doctor or pharmacist tells you to stop taking Zarontin or the capsules or syrup have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Zarontin capsules 250 mg are clear orange soft gelatin capsules, available in bottles of 200 capsules.

Zarontin syrup is a clear yellow to pink solution, available in a 200 mL bottle.

Ingredients

Zarontin capsules contain:

Ethosuximide 250 mg as the active ingredient.

The capsules also contain:

- * macrogol 400
- * gelatin
- * glycerol
- * sorbitol
- * vanillin
- * methyl hydroxybenzoate
- * propyl hydroxybenzoate
- * sunset yellow FCF

Zarontin Syrup contains:

Ethosuximide 250 mg/5 mL as the active ingredient.

The syrup also contains:

- * sodium citrate
- * sodium benzoate
- * saccharin sodium
- * sucrose
- * glycerol
- * imitation raspberry flavour
- * purified water
- * citric acid monohydrate

Supplier

Zarontin is supplied in Australia by:

Pfizer Australia Pty Limited
 ABN 50 008 422 348
 38-42 Wharf Road
 West Ryde NSW 2114
 Australia

Toll Free number: 1800 675 229

Zarontin is supplied in New Zealand by:

Pfizer New Zealand Ltd
 PO Box 3998
 Auckland, New Zealand.

Toll Free number: 0800 736 363

Australian Registration Numbers:

250 mg capsules: AUST R 94175
 250 mg/5 mL syrup: AUST R 79031

This leaflet was revised on 03 March 2008

(C) Pfizer Australia Pty Ltd
 All rights reserved