Package leaflet: Information for the patient

ZARONTIN® 250 mg/5 ml Syrup

ethosuximide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Zarontin is and what it is used for
2. What you need to know before you take Zarontin
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1. What Zarontin is and what it is used for

Zarontin contains the active substance ethosuximide which is one of a group of medicines called anti-epileptic drugs; these medicines are used to treat epilepsy.

Zarontin can be used for the treatment of absence seizures (a form of epilepsy) in adults, elderly and children and may be taken with other anti-epileptic drugs.

You should consult your doctor if you are unsure why you have been given Zarontin 250 mg/5ml Syrup, if you do not feel better or if you feel worse.

2. What you need to know before you take Zarontin

Do not take Zarontin:
- if you are allergic to ethosuximide, or any of the other ingredients in this medicine (listed in section 6).

Warnings and precautions

Serious skin reactions including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Zarontin treatment. Stop using Zarontin and seek medical attention immediately if you notice any of the symptoms described in section 4. These symptoms often occur within 28 days of starting this medicine, but can happen later.

Talk to your doctor or pharmacist before taking Zarontin if you suffer from or have suffered in the past from any of the following conditions:
- Liver disease.
- Kidney disease.
- Bruising, fever, looking pale or a severe sore throat. These may be the first signs of a potentially serious blood disorder, which could be fatal if not detected.

Your doctor may take regular blood and/or urine samples to test for these.

Pay special attention to symptoms of bone marrow depression such as fever, inflammation of throat or pharynx tonsils as well as haemorrhagic tendency, and consult your doctor, if you experience any of these symptoms.
Your blood count should be checked regularly (initially monthly, after one year every six months) to identify potential injury of the medulla. Your liver enzymes should also be checked regularly.

If you are taking anti-epileptic drugs, your doctor will routinely assess you for depression, anxiety and suicidality. If you are taking anti-epileptic drugs and you feel depressed and anxious, the symptoms of which are feeling low, loss of interest in everyday activities, lack of energy and a general feeling of unease, please consult your doctor.

A small number of people being treated with anti-epileptics such as ethosuximide have had thoughts of harming or killing themselves. If at any time you have these thoughts, immediately contact your doctor.

Other medicines and Zarontin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can affect the way Zarontin works, or Zarontin itself can reduce the effectiveness of other medicines taken at the same time. These include:
- Other medicines used for epilepsy (phenytoin, sodium valproate and valproic acid).

Your doctor may need to test the amount of these medicines in your blood to help decide if any of these medicines are affecting your treatment.

Zarontin with food and drink

Zarontin can be taken before or after food and drink.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

You should not take Zarontin if you are breast-feeding.

Driving and using machines

Zarontin may cause dizziness or drowsiness. If you experience these symptoms, do not drive or use any tools or machinery.

Zarontin contains sucrose, glucose, sodium benzoate (E211), propylene glycol (E1520) and sodium

This medicine contains sucrose and glucose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This medicine may be harmful to the teeth.

This medicine contains 12 mg sodium benzoate (E211) in each 5 ml syrup which is equivalent to 2.4 mg/ml. Sodium benzoate (E211) may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

This medicine contains 42 mg propylene glycol (E1520) in each 5 ml syrup which is equivalent to 8.4 mg/ml. If your baby is less than 4 weeks old, talk to your doctor or pharmacist before giving them this medicine, in particular if the baby is given other medicines that contain propylene glycol or alcohol.

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml syrup, this is to say essentially 'sodium-free'.

3. How to take Zarontin

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor if you are not sure.

Shake the bottle vigorously before you measure your dose.
The pack contains a measuring cup graduated from 2 ml to 15 ml to adjust the doses. Use the measuring cup to take the dose prescribed by your doctor. Wash and dry the measuring cup after each use.

It is best to take Zarontin at the same time each day. Zarontin can be taken before or after food and drink.

Adults and children over 6 years

The amount of Zarontin needed varies from one person to another. Most adults and children over 6 years usually start on 10 ml (500 mg) a day and build up to 20 ml to 30 ml (1000 mg to 1500 mg) a day, with increments of 250 mg every 5 to 7 days. Occasionally, 40 ml (2000 mg) a day may be necessary.

Children under 6 years

Infants and children usually start on 5 ml (250 mg) a day and build up to a dose that controls their symptoms gradually by small increments every few days until control is achieved. The maximum dose is 20 ml (1000 mg) a day.

If you take more Zarontin than you should

If you accidentally take too much Zarontin contact your doctor at once or go to the nearest hospital casualty department. Always take the labelled medicine package with you, whether there is any Zarontin left or not.

If you forget to take Zarontin

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Zarontin
Do not stop taking Zarontin unless your doctor tells you to. If you suddenly stop taking this medicine you may have a seizure. Should you need to stop taking Zarontin, your doctor will decide which method is best for you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Zarontin and seek medical attention immediately if you notice any of the following symptoms:

- Reddish patches on the trunk, the patches are target-like macules or circular, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome) (Uncommon (may affect up to 1 in 100 people)).
- Widespread rash, high body temperature and enlarged lymph nodes (drug reaction with eosinophilia and systemic symptoms (DRESS)) (Frequency not known). If these are severe and you also experience pain and inflammation of the joints this could be related to a condition called Systemic Lupus Erythematosus (Uncommon (may affect up to 1 in 100 people)).

Seek medical attention if you notice any of the following symptoms:

- Changes in your blood (bruising or bleeding more easily, fever, you are looking pale or you have a severe sore throat, mouth ulcers, fatigue, repeated infections or infections that will not go away). These may be the first signs of an abnormality of the blood, including decreases in the number of red cells, white cells or platelets and bone marrow suppression, please consult your doctor. Your doctor may take regular blood samples to test for these effects (Uncommon (may affect up to 1 in 100 people)).
- If you experience an increase in the number of your generalized fits (tonic-clonic seizures) (Frequency not known).

Other side-effects that may occur are:

- **Common side effects (may affect up to 1 in 10 people):** decreased appetite, headaches, unsteadiness, difficulty in controlling movements, dizziness, drowsiness, stomach ache and cramps, feeling sick, being sick (vomiting), skin rash including measles-like reactions which are mild, hives.
- **Uncommon side effects (may affect up to 1 in 100 people):** aggressive behaviour, nightmares, depression, thinking about suicide, psychotic disorder, disturbance to sleep patterns, shaking, abnormal or uncoordinated movements, sluggishness, inability to concentrate, short sightedness, hiccups, diarrhoea, enlarged gums, swollen tongue, blood in the urine, vaginal bleeding, fatigue, irritability, weight loss, feelings of persecution, hyperactivity, changes to your blood counts, particularly white blood cells called eosinophils.
- **Not known (frequency cannot be estimated from the available data):** Sense of great well-being, an increased sex drive, extreme restlessness, loss of interest in activities, violent muscle contractions, swelling of the lymph glands.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zarontin

Keep this medicine out of the sight and reach of children.
Do not store above 25 °C.
Do not use this medicine after the expiry date which is stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What Zarontin contains
The active ingredient is ethosuximide.
Each 5 ml dose contains 250 mg of ethosuximide.

The other ingredients are sodium citrate dihydrate, sodium benzoate (E211), sachharin sodium, sucrose, glycerol, artificial raspberry flavour (including glucose and propylene glycol (E1520)), citric acid monohydrate, purified water (see section 2 Zarontin contains sucrose, glucose, sodium benzoate (E211), propylene glycol (E1520) and sodium).

What Zarontin looks like and contents of the pack
Zarontin 250 mg/5 ml Syrup is a clear yellowish to pinkish dye free raspberry flavoured syrup.
Zarontin Syrup is available in 200 ml amber glass bottles with a child-resistant cap and a measuring cup graduated from 2 ml to 15 ml.

Manufacturer
Delpharm Orléans or Famar Orleans, 5 Avenue de Concyr, 45071 Orleans, Cedex 2, France.

Product procured from within the EU, repackaged and distributed by the parallel product authorisation holder who is: PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Zarontin is a registered trademark of Essential Pharma Limited.

Parallel Product authorisation Number: PPA0465/456/001

This leaflet was last revised in January 2024