Zarontin® 250mg/5ml Syrup

2039
02.03.23[17]

(ethosuximide)

Patient Information Leaflet
The name of your medicine is Zarontin® 250mg/5ml Syrup but will be referred to as Zarontin throughout this leaflet.

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
This medicine contains 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) 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 (hypersensitive) to ethosuximide, or any of the other ingredients in this medicine (listed in section 6).

Warnings and precautions
Tell your doctor or pharmacist immediately if you develop a severe rash characterised by fever, abdominal pain, swelling of the tongue and face and/or blistering of the skin, mouth, eyes and genitals, as this medicine may need to be discontinued. These symptoms often occur within 28 days of starting this medicine, but can happen later.

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.**

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.

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, including medicines obtained without a prescription.

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, 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 and glucose
Sucrose and glucose are types of sugars. 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.

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.
Always use a medicine spoon or measure.

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 two 5 ml spoonfuls (500 mg) a day and build up to four to six 5 ml spoonfuls (1000 mg to 1500 mg) a day, with increments of 250 mg every 5 to 7 days. Occasionally eight 5 ml spoonfuls (2000 mg) a day may be necessary.

Children under 6 years
Infants and children usually start on one 5 ml spoonful (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 four 5ml spoonfuls (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).
- **Widespread rash, high body temperature and enlarged lymph nodes (drug reaction with eosinophilia and systemic symptoms (DRESS)).**

Tell your doctor **immediately** if you experience any of the following symptoms after taking this medicine. Although they are very rare, these symptoms can be serious.
- If you develop a severe skin rash that causes blistering, this can affect the mouth and tongue. These may be signs of a condition known as Stevens Johnson Syndrome. Your doctor will stop your treatment in this case.
- If you notice bruising, fever, you are looking pale or you have a severe sore throat. 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.
- Skin rash and fever with swollen glands, as these may be signs of a hypersensitivity reaction or a particular allergic reaction known as DRESS syndrome. 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.
- If you experience an increase in the number of your generalized fits (tonic-clonic seizures).

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.

- **Not known (frequency cannot be estimated from the available data):** Stevens-Johnson Syndrome: Serious illness with blistering of the skin, mouth, eyes and genitals accompanied with fever. DRESS: Fever, severe rash, joint pain, enlarged lymph nodes and inflammation of one or more internal organs such as the liver leading to abdominal pain, yellowing of the skin and the whites of the eyes and/or heart, lungs and kidneys; with changes to your blood counts, particularly white blood cells called eosinophils. Sense of great wellbeing, an increased sex drive, extreme restlessness, loss of interest in activities, violent muscle contractions, hair loss, swelling of the lymph glands.
  Changes in your blood (**bruising or bleeding more easily,** fever, sore throat, mouth ulcers, fatigue, repeated infections or infections that will not go away). Your doctor may take regular blood samples to test for these effects.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Zarontin
Keep out of the sight and reach of children.

Do not store above 25ºC.

Do not use Zarontin after the expiry date which is stamped on the pack. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater of household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.
If your medicine becomes discoloured or shows any other signs of deterioration, seek the advice of a pharmacist.

6. Contents of the pack and other information
What Zarontin Syrup contains
Each 5ml of syrup contains 250mg of the active ingredient ethosuximide.
The other ingredients are sodium citrate, sodium benzoate (E 211), saccharin sodium, sucrose, glycerol (E 422), raspberry flavour (contains in particular glucose and propylene glycol (E1520)), citric acid monohydrate and water.

What Zarontin looks like and contents of the pack
Zarontin is available in amber round glass bottle stoppered with aluminium screw cap and a measuring cup containing 200 ml of clear, colourless, raspberry flavoured syrup.

Manufacturer and Product Licence holder
Manufactured by
Delpharm Orleans, 5 Avenue de Concyr, 45071 Orleans, Cedex 02, France.
Procured from within the EU by Product Licence holder Tenolol Ltd. 5, Sandridge Close, Harrow, HA1 1XD. Repackaged by Servipharm Ltd.

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This leaflet was last updated on 02.03.23[17]

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Ethosuximide Tenolol 250mg/5ml Syrup

2039
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Patient Information Leaflet
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- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
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What is in this leaflet

1. What Ethosuximide is and what it is used for
This medicine contains ethosuximide which is one of a group of medicines called anti-epileptic drugs; these medicines are used to treat epilepsy.

Ethosuximide can be used for the treatment of absence seizures (a form of epilepsy) and may be taken with other anti-epileptic drugs.

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

2. What you need to know before you take Ethosuximide
Do not take Ethosuximide
- if you are allergic (hypersensitive) to ethosuximide, or any of the other ingredients in this medicine (listed in section 6).

Warnings and precautions
Tell your doctor or pharmacist immediately if you develop a severe rash characterised by fever, abdominal pain, swelling of the tongue and face and/or blistering of the skin, mouth, eyes and genitals, as this medicine may need to be discontinued. These symptoms often occur within 28 days of starting this medicine, but can happen later.

Serious skin reactions including Stevens-Johnson syndrome and **drug reaction with eosinophilia and systemic symptoms (DRESS)** have been reported in association with Ethosuximide treatment. **Stop using Ethosuximide and seek medical attention immediately if you notice any of the symptoms described in section 4.**

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- Liver disease.
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Ethosuximide with food and drink
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Ethosuximide contains sucrose and glucose
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