

## Package leaflet: Information for the user

### Ethosuximide Essential Generics 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 Ethosuximide Syrup is and what it is used for
2. What you need to know before you take Ethosuximide Syrup
3. How to take Ethosuximide Syrup
4. Possible side effects
5. How to store Ethosuximide Syrup
6. Contents of the pack and other information

#### **1. What Ethosuximide Syrup is and what it is used for**

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

It is used to control epilepsy in children and adults.

Epilepsy is a condition where you have repeated seizures (fits).

Ethosuximide is used to control brief, sudden loss of consciousness (absence seizures, also called petit mal), and uncontrolled jerking movements (myoclonic seizures).

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

#### **2. What you need to know before you take Ethosuximide Syrup**

##### **Do not take Ethosuximide Syrup:**

- if you are allergic to ethosuximide, or any of the other ingredients of this medicine (listed in section 6).
- if you have porphyria (a metabolism disorder which causes abdominal pain and mental disorder).

If any of the above apply to you, speak to your doctor or pharmacist.

#### **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 Ethosuximide Syrup treatment. Stop using Ethosuximide Syrup 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 Ethosuximide Syrup 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 Ethosuximide Syrup**

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

Some medicines may be affected by Ethosuximide Syrup or they may affect how well Ethosuximide Syrup will work.

Tell your doctor or pharmacist if you are taking:

- isoniazid, a medicine used for certain types of infections
- other medicines used for epilepsy, in particular carbamazepine, phenytoin, sodium valproate and valproic acid. If Ethosuximide Syrup is to replace your other medicines for epilepsy, your doctor will withdraw these gradually to avoid seizures.

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.

### **Ethosuximide Syrup with food and drink**

Ethosuximide Syrup 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 for advice before taking this medicine.

You should not take Ethosuximide Syrup if you are breast-feeding.

### **Driving and using machines**

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

### **Ethosuximide Syrup contains sucrose, other sugars and sodium**

This medicine contains 3.05 g of sucrose and between 0.16 g and 0.22 g of other sugars per 5 ml syrup. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.

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

### **3. How to take Ethosuximide Syrup**

Always take this medicine exactly as your doctor has told you.

Your doctor will decide on the appropriate dose to suit your condition. Check with your doctor or pharmacist if you are not sure.

- It is important to take the medicine at the right time and regularly, as directed by your doctor.
- After taking Ethosuximide Syrup, rinse the mouth or brush the teeth - the syrup contains sucrose which may be harmful to the teeth.
- Take the syrup with or without food, whichever you prefer.
- Older children and adults may be given ethosuximide in a capsule form.

#### **Recommended dose**

**Adults, elderly and children over 6 years:** the usual starting dose is 10 ml a day.

Your doctor may increase your dose by 5 ml a day every 5 to 7 days until your epilepsy is well controlled.

A maximum dose of 40 ml a day, taken in divided doses, may occasionally be necessary. Do NOT change the dose yourself.

**Children under 6 years:** 5 ml a day.

Your doctor may increase the dose slowly to a maximum of 20 ml daily.

**Blood tests** may be carried out to check the level of ethosuximide in your body.

#### **If you take more Ethosuximide Syrup than you should**

If you take more syrup than you should, you may feel very drowsy or confused.

1. Tell your doctor, pharmacist or nearest hospital casualty department immediately.
2. Take the bottle and any remaining syrup with you so that people can see what you have taken.
3. Do this even if you feel well.

#### **If you forget to take Ethosuximide Syrup**

If you forget to take a dose take it as soon as you remember, but if it is almost time for your next dose skip the missed dose and continue as usual.

Do not take a double dose to make up for a forgotten dose.

#### **If you stop taking Ethosuximide Syrup**

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

Ethosuximide Syrup helps to control your condition but does not cure it. Therefore, you must take your medicine every day, even if you feel well.

Do not let yourself run out of medicine, especially over the weekends or on holidays.

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 Ethosuximide Syrup 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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 Ethosuximide Syrup

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle label and on the carton after EXP. The expiry date refers to the last day of that month.

Store below 30°C. Do not refrigerate or freeze.

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 protect the environment.

## **6. Contents of the pack and other information**

### **What Ethosuximide Syrup contains**

- The active substance is ethosuximide. Each 5 ml of the syrup contains 250 mg ethosuximide.
- The other ingredients are sucrose, water, blackcurrant juice, saccharin sodium. (See end of Section 2 for further information on sucrose and sodium).

### **What Ethosuximide Syrup looks like and contents of the pack**

Ethosuximide Syrup is a dark red-brown liquid with the smell and flavour of blackcurrant. It is available in amber glass bottles of 200 ml with tamper evident child resistant polypropylene/polyethylene white cap.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder**

Essential Pharma Ltd., 7 Egham Business Village, Crabtree Road, Egham, Surrey, TW20 8RB.

#### **Manufacturer**

WASDELL PACKAGING LIMITED,  
UNITS 1, 2, 3, 5, 6, 7 & 8 EURO WAY INDUSTRIAL ESTATE,  
BLAGROVE, SWINDON, SN5 8YW,  
United Kingdom

Delpharm Bladel B.V., Industrieweg 1, 5531 AD Bladel, The Netherlands.

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