Package leaflet: Information for the user

Ethosuximide Roma 250mg/5ml oral solution

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 symptoms 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 ROMA IS AND WHAT IT IS USED FOR

What Ethosuximide Roma is

Ethosuximide Roma 250mg/5ml oral solution (called Ethosuximide Roma in this leaflet) contains a medicine called ethosuximide. Ethosuximide Roma is a medicine for the treatment of epileptic fits (anti-epileptic).

What Ethosuximide Roma is used for

Ethosuximide Roma is used to treat

- Pyknoleptic absences and complex and atypical absences.
- Myoclonic-astatic petit mal and myoclonic fits of adolescents (impulsive petit mal), if other medicines are not effective and/or are not tolerated.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ETHOSUXIMIDE ROMA

Do not take Ethosuximide Roma if:

- you are allergic (hypersensitive) to ethosuximide, other succinimides or any of the other ingredients of this medicine (listed in Section 6).

Warnings and precautions

Talk to your doctor before taking Ethosuximide Roma, if:

- you have kidney or liver problems
- you are pregnant or planning a pregnancy, or if you are breast-feeding
- you have a history of mental illness.

If you experience movement disorders (see section 4) do not continue taking Ethosuximide Roma. Please contact the nearest doctor who, in the event of significant disturbances, can administer diphenhydramine as an antidote by the intravenous route.

Pay special attention to symptoms of bone marrow depression such as fever, inflammation of the 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.

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 Roma and seek medical attention immediately if you notice any of the symptoms described in section 4.

Psychic side effects (anxiety, illusion) can occur in particular in patients with a history of psychiatric disorders. Special caution is required when Ethosuximide Roma is administered to this group of patients.

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, contact your doctor **immediately**.

Note:

To prevent grand mals which are often associated with complex and atypical absences, ethosuximide can be combined with effective anti-epileptics (e.g. primidone or phenobarbital).

Additional grand mal prophylaxis can be dispensed with only in the case of pyknoleptic absence epilepsies in children of school age.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Ethosuximide Roma.

Other medicines and Ethosuximide Roma

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

In particular, tell your doctor if you are taking any of the following:

- Other medicines used to control epilepsy, especially **carbamazepine, phenytoin, primidone, phenobarbital and sodium valproate**.

If ethosuximide is being used to replace another medicine for epilepsy your doctor will withdraw these gradually to stop you getting seizures.

Pregnancy, breast-feeding and fertility

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.

Pregnancy

Before you start taking ethosuximide:

- **If you are of child bearing age and are planning to become pregnant** talk to your doctor for advice before you start taking ethosuximide.

If you become pregnant while taking ethosuximide:

- Tell your doctor **immediately**.
- Do not stop taking Ethosuximide Roma without telling your doctor as your fits may start again. Your doctor may reduce your dose, but it is still important for your fits to be controlled.
- Ethosuximide crosses the placenta which may increase the risk of foetal abnormalities. Discuss the need for any diagnostic tests with your doctor or other healthcare professionals.
- It is recommended that pregnant women take Folic Acid and Vitamin K supplements.

Breast-feeding

Ethosuximide passes into breast milk.

DO NOT breast-feed while taking Ethosuximide Roma as it will make your baby sleepy, not able to suckle properly or become irritable or unsettled.

Driving and using machines

You may feel drowsy while you are taking this medicine, particularly when you first start taking it. **DO NOT drive** or use any tools or machines until your doctor tells you it is OK to do so.

Important information about some of the ingredients of Ethosuximide Roma

This medicine contains:

- **Sodium Benzoate (E211):** This medicine contains 2.5 mg sodium benzoate in each 5ml dose which is equivalent to 10mg/20ml. Sodium Benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- **Sodium**: This medicine contains less than 1mmol sodium (23mg) per 20ml, that is to say essentially 'sodium-free'.
- **Propylene glycol (E1520):** This medicine contains 3.7mg propylene glycol in each 5ml. 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.

3. HOW TO TAKE ETHOSUXIMIDE ROMA

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

- **For oral use only.** Take this medicine by mouth.
- Shake the bottle before use.
- Use the syringe provided and read the dosing instructions below.

How much to take

Your doctor will decide the dose appropriate for you or your child.

Adults, the elderly and children over 6 years

- The starting dose is 500mg (10ml) daily.
- Your doctor may decide to increase your dose every 5-7 days until your fits are under control.
- The maximum dose is 2000mg (40ml) in divided doses.

Children between 2 and 6 years

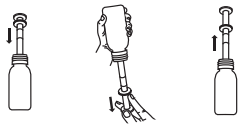
- The starting dose is one 250mg (5ml) daily.
- Your doctor may decide to increase this every few days until your child's fits are under control.
- The dose will be calculated on the weight of your child to a maximum of 1000mg (20ml) each day.

Children under 2 years

- The starting dose is one 125mg (2.5ml) daily.
- Your doctor may decide to increase this every few days until your child's fits are under control.
- The dose will be calculated on the weight of your child to a maximum of 1000mg (20ml) each day.

Using the dosing syringe

- When you use the medicine for the first time, place the adaptor in the neck of the bottle.
- Push the syringe firmly into the adaptor in the neck of the bottle.
- To fill the syringe, turn the bottle upside down. Whilst holding the syringe in place, gently pull the plunger down drawing the medicine to the correct mark on the syringe. Your doctor will tell you the right dose for you or your child.
- Turn the bottle the right way up, remove the syringe from the adaptor by gently twisting the syringe.
- Place the end of the syringe into the mouth and gently press the plunger down to slowly and gently release the medicine.
- After use replace the bottle cap. Wash the syringe in warm water and allow to dry. Store out of reach of children.



If you take more Ethosuximide Roma than you should

- If you take more Ethosuximide Roma than you should, or if you think a child has accidently swallowed any, tell a doctor or go to a hospital casualty department straight away. Take this leaflet with you. This is so the doctor knows what you have taken.
- Taking too much ethosuximide can be very dangerous. You may feel or be sick, feel drowsy or confused or struggle to breathe.

If you forget to take Ethosuximide Roma

- If you forget a dose, take the next dose as soon as you remember. However, if it is nearly time for the next dose skip the missed dose.
- **Do not** take a double dose to make up for the forgotten dose.

If you stop taking Ethosuximide Roma

- Keep taking Ethosuximide Roma until your doctor tells you to stop.
- **Do not** stop taking Ethosuximide Roma just because you feel better. Your fits will not be controlled if you stop taking your medicine.
- If required, your doctor will tell you how to stop taking your medicine in a gradual way.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. Children are at higher risk of the effects.

Serious side effects

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

- You have an allergic reaction. The signs may include: a rash, problems swallowing or breathing, swelling of your lips, face, throat or tongue.
- 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 or pharmacist straight away if you have any of the following side effects:

- 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.
- Skin rash and fever with swollen glands, as these may be signs of a hypersensitivity reaction. 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.
- Increased seizures (fits). Blood tests may be carried out and your doctor may adjust the dose.
- Suicidal thoughts or feel depressed.

Other side effects are:

Common (affects between 1 in 10 and 1 in 100 people)

- Abdominal pain, upset stomach, feeling and being sick
- Hiccups

Uncommon (affects between 1 in 100 and 1 in 1,000 people)

- Anxiety
- Disturbed sleep
- Lethargic, tired or irritable
- Ataxia (movement disorders)
- Feeling withdrawn
- Severe headaches
- Loss of appetite
- Weight loss
- Constipation or diarrhoea

Rare (affects between 1 in 1000 to 1 in 10,000 people)

- Changes in your blood. You will have regular blood tests.
- Feeling paranoid, or having hallucinations which may develop over days or weeks of treatment.
- A condition called Lupus erythematodes, symptoms can include; painful or swollen joints, fever, chest pain, hair loss, mouth ulcers, swollen lymph nodes and a red rash, usually on the face.

Not known (frequency cannot be estimated from the available data)

- Uncontrolled, involuntary movements when you first start treatment.
- Fatigue or more prone to infection caused by low levels of cells in your blood (anaemia or panocytopenia).
- Allergic skin reactions such as rash, Stevens-Johnson syndrome (very severe allergic skin reaction).

Note: Long-term treatment may affect the patient's performance, e.g. the performance in school of children and adolescents.

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 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 ETHOSUXIMIDE ROMA

This medicine does not require any special storage conditions.

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

After first opening use within two months.

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

Do not dispose of any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Ethosuximide Roma contains

- Each 5ml of oral solution contains 250 mg of the active substance ethosuximide.
- The other ingredients are: glycerol, sodium benzoate (E211), sucralose (E955), citric acid anhydrous (E330), sodium citrate, strawberry flavour (including propylene glycol, E1520), hydrochloric acid and purified water.

What Ethosuximide Roma looks like and contents of the pack

Ethosuximide Roma is a strawberry flavoured clear, colourless solution.

Ethosuximide Roma is packed in amber glass bottles containing 200ml sealed with a child-resistant, tamper-evident screw cap. It comes with a 10ml oral syringe, with 0.5ml graduations, and a bottle neck adaptor.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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