Package leaflet: Information for the user

Ethosuximide Roma 500 mg/5 ml 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 500 mg/5 ml 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
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).

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).
- you have porphyria (a metabolism disorder which causes abdominal pain and mental disorder).

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 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 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.

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.

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.

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**.

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, lamotrigine and sodium valproate**.
- **Isoniazid**, a medicine used for certain types of infection.

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 can be considered as sugar-free.
This medicine contains:
- **Sodium Benzoate (E211):** This medicine contains 2.5 mg sodium benzoate in each 5 ml of oral solution which is equivalent to 5 mg per 10 ml of oral solution. 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 1 mmol sodium (23 mg) per 10 ml of oral solution, that is to say essentially 'sodium-free'.
- **Propylene glycol (E1520):** This medicine contains 3.7 mg propylene glycol in each 5 ml of oral solution. 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.

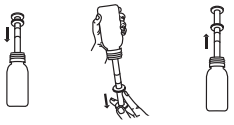
How much to take
Your doctor will decide the dose appropriate for you or your child.

Adults, the elderly and children over 6 years
- The starting dose is 500 mg (5 ml) daily.
- Your doctor may decide to increase your dose every 5-7 days until your fits are under control.
- The maximum dose is 2000mg (20ml) in divided doses.

Children between 2 and 6 years
- The starting dose is one 250 mg (2.5 ml) 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 1000 mg (10 ml) each day.

Children under 2 years
- The starting dose is one 125 mg (1.25 ml) 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 1000 mg (10 ml) 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:
- 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 are:
Common (may affect up to 1 in 10 people)
- decreased appetite,
- headaches,
- unsteadiness,
- difficulty in controlling movements,
- dizziness,
- drowsiness,
- stomach ache and cramps,
- feeling sick or being sick (vomiting),
- skin rash including measles-like reactions which are mild,
- hives.

Uncommon (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 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 6 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 5 ml of oral solution contains 500 mg of the active substance ethosuximide.
- The other ingredients are: glycerol (E422), sodium benzoate (E211), sucralose (E955), citric acid (E330), sodium citrate (E331 iii), strawberry flavour (including propylene glycol, E1520), hydrochloric acid, concentrated (E507) (for pH adjustment) and purified water.

What Ethosuximide Roma looks like and contents of the pack
Ethosuximide Roma is a clear, colourless solution with characteristic strawberry odour.
Ethosuximide Roma is packed in amber glass bottles containing 200 ml sealed with a child-resistant, tamper-evident screw cap. It comes with a 10 ml oral syringe, with 0.25 ml graduations, and a bottle neck adaptor.

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