Package leaflet: Information for the user

Ethosuximide Medley 250 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 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 Medley is and what it is used for

The name of your medicine is Ethosuximide Medley 250 mg/5 ml Oral Solution, and is referred to as Ethosuximide Medley throughout this leaflet.

Ethosuximide Medley 250 mg/5 ml Oral Solution contains the active substance ethosuximide.
Ethosuximide Medley is a medicine used to treat epileptic fits (anti-epileptic).

This medicine 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 Medley

Do not take Ethosuximide Medley
- if you are allergic to ethosuximide, other succinimides (group of medicines to which ethosuximide belongs) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor before taking Ethosuximide Medley.
- If you experience movement disorders (listed in section 4) do not continue taking this medicine. 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 throat or pharynx tonsils as well as bleeding tendency, and consult your doctor, if you experience any of these symptoms.
  The blood count should be checked regularly (initially monthly, after one year every six months) to identify potential injury of the medulla. At a leucocyte count (number of white blood cells) of less than 3500/mm^3 or a granulocyte ratio of less than 25 % the dose should be reduced or Ethosuximide Medley discontinued completely. The liver enzymes should also be checked regularly.
- Psychiatric side effects (anxiety,agitation, paranoid behaviour and hallucinations) can occur in patients with a history of psychiatric disorders. Special caution is required when Ethosuximide Medley is administered to this group of patients. A small number of patients treated with anti-epileptics such as ethosuximide have developed thoughts about self-harm or suicidal thoughts. If at any time during the treatment you have such thoughts, tell your doctor immediately.
- 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 Medley and seek medical attention immediately if you notice any of the symptoms described in section 4.

Note: To prevent grand mals (a type of seizure) which are often associated with a loss of consciousness and violent muscle contractions, this medicine can be combined with effective anti- epileptic medicines (such as primidone or phenobarbital). This additional treatment to prevent seizures (fits) can be used only in the case of childhood (in children of school age) epilepsy syndrome characterized by frequent absence of seizures (called pyknolepsy absence epilepsy).

Other medicines and Ethosuximide Medley
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Other medicines that affect the efficacy of Ethosuximide Medley:
- In patients also taking carbamazepine (medicine for the treatment of epileptic fits), the plasma clearance (excretion rate) of ethosuximide, the active substance of Ethosuximide Medley, may be elevated.
- In patients taking valproic acid (medicine for the treatment of epileptic fits), the concentration of ethosuximide in blood may rise.
- CNS depressants and Ethosuximide Medley may mutually increase their sedative (calming and sleep inducing) effects.

Other medicines affected by Ethosuximide Medley:
Ethosuximide normally does not change the concentration of other medicines for the treatment of epileptic fits (such as, primidone, phenobarbital, phenytoin) in blood. In individual cases the phenytoin level in blood may rise, however.

Ethosuximide Medley with alcohol
Alcohol can change and increase the effects of Ethosuximide Medley in an unforeseeable manner. Do not drink alcohol or consume alcohol-containing food while you take Ethosuximide Medley.

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.

Pregnancy
If you are of childbearing age, you should be advised by your doctor regarding the necessity of planning and monitoring any pregnancy before starting the treatment with Ethosuximide Medley. Do not discontinue Ethosuximide Medley without first consulting your doctor as epileptic seizures might recur, which could harm you and/or your unborn child.

No specific malformations of babies are known, which were caused by the treatment with ethosuximide. However, patients treated with medicines against epileptic seizures generally have a higher risk for malformations than other women. The most commonly reported malformations are cleft lip, cardiovascular malformation and neural tube defects (spina bifida). This risk is even higher in patients treated with more than one anti-epileptic, and therefore combination treatment should be avoided during pregnancy.

Prenatal (before birth) diagnostic measures like high level ultrasound and the determination of – α fetoprotein are recommended for the early detection of foetal damage.

Do not exceed the lowest effective ethosuximide dose ensuring seizure control, particularly between the 20th and 40th day of pregnancy. Your ethosuximide serum concentration must be checked regularly. You should take extra folic acid, if you are planning to have a baby or if you are pregnant.

To prevent vitamin K1 deficiency in your baby and bleeding caused by this deficiency, you should also be given vitamin K1 during the last month of your pregnancy.

Breast-feeding
You should not take Ethosuximide Medley if you are breast-feeding.
Ethosuximide passes into breast milk and might lead to sedation, poor suckling and irritability in breast-fed infants. Therefore, you should stop breast-feeding during treatment with Ethosuximide Medley.

Driving and using machines
Ethosuximide Medley can affect reactivity. During the adjustment phase you are not able to respond quickly and purposefully to unexpected and sudden events. Do not drive cars or other vehicles! Do not operate dangerous electric tools or machines! Do not work without a secure hold!

The decision about whether you are able to drive and use machines will be taken in each case by your doctor considering your individual response to the medicine. Be advised that alcohol further impairs your driving capacity.

Ethosuximide Medley Oral Solution contains sucrose and propylene glycol (E1520)
- This medicine contains 3 g sucrose per 5 ml, equivalent to 0.6 g sucrose per ml.
  This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. It may be harmful to teeth.
- This medicine contains 0.00075 mg of alcohol (ethanol) in each 5 ml which is equivalent to 0.00015 mg/ml (0.000015% w/v). The amount in 5 ml of this medicine is equivalent to less than 1 ml beer or 1 ml wine.
  The small amount of alcohol in this medicine will not have any noticeable effects.
- This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'.

3. How to take Ethosuximide Medley

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

Dosage
Unless otherwise prescribed by your doctor, the recommended dose is:

Adults, elderly patients and children over 6 years of age:
The treatment is started at a daily dose of 500 mg (10 ml). Depending on the patient's tolerance, the dose is increased every five to seven days in increments of max. 250 mg (5 ml) until the fits are controlled by a daily dose of 1000-1500 mg (20-30 ml). In an individual case, a daily dose of 2000 mg (40 ml), taken in several single doses, may be required.

The therapeutic plasma level of ethosuximide is normally between 40 and 100 microgram per ml. However, the dose depends on the patient's clinical response. The half-life of ethosuximide in plasma is more than 24 hours so that the daily dose can be taken as a single dose provided the medicine is well tolerated. Higher daily doses should be taken in 2 or 3 single doses.
The decision about changes to the dosage regimen can be taken by your doctor only.
The risk of side effects which depend on the dose taken can be reduced by taking small initial doses of Ethosuximide Medley and increasing them gradually to optimum amounts (increasing the amounts slowly from day to day) and by taking them during or after meals.

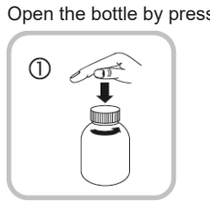
Use in haemodialysis patients
Ethosuximide is dialysable. Haemodialysis patients therefore require a supplementary dose or a modified dosage regimen. During a dialysis period of four hours, 39 % to 52 % of the dose taken is removed.

Use in children and adolescents
Children under 2 years:
The treatment is started at a daily dose of 125 mg (2.5 ml).
The dose is increased gradually in small increments every few days until the fits are controlled.

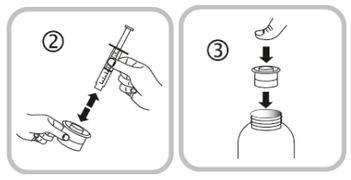
Use in children between 2 and 6 years of age
The treatment is started at a daily dose of 250 mg (5 ml). The dose is increased gradually in small increments every few days until the fits are controlled. The optimum daily dose for most children is 20 mg per kg. The maximum dose is 1000 mg (20 ml).

Method of administration
Ethosuximide Medley is for oral use. The solution can be taken during or after meals. Always use a graduated syringe while administering this medicine. Syringe should be rinsed thoroughly using water after administration.

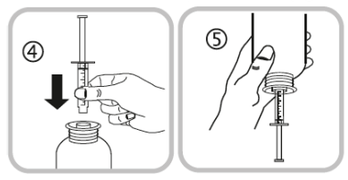
Instructions for the use of syringe:
Open the bottle by pressing the cap while turning it anti-clockwise (figure 1).



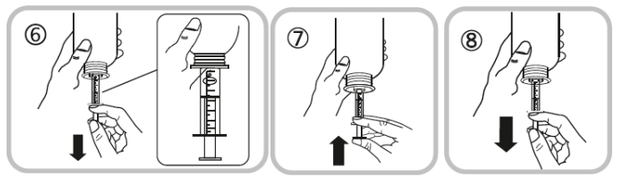
Follow these steps the first time you take Ethosuximide Medley:
- Take off the adaptor from the oral syringe (figure 2).
- Put the adaptor into the top of the bottle (figure 3). Make sure it is fixed well in place. You do not need to remove the adaptor after use.



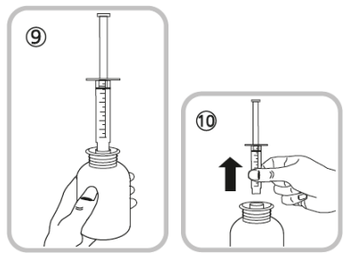
Follow these steps each time you take Ethosuximide Medley:
- Put the oral syringe into the adaptor opening (figure 4).
- Turn the bottle upside down (figure 5).



- Hold the bottle upside down in one hand and use the other hand to fill the oral syringe.
- Pull the piston down to fill the oral syringe with a small amount of solution (figure 6).
- Push the piston up to get rid of any bubbles (figure 7).
- Pull the piston down to the milliliter (ml) dose marker prescribed by your doctor (figure 8).



- Turn the bottle the right way up (figure 9).
- Take the oral syringe out of the adaptor (figure 10).



Pharmacode

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- empty the contents of the oral syringe into the patients mouth by pushing the piston to the bottom of the oral syringe (figure 11).

- Close the bottle with the plastic screw cap (you do not need to remove the adaptor).
- Wash the oral syringe with water only (figure 12).

How long to take Ethosuximide Medley
The treatment of epileptic fits is principally a long-term treatment. The dose, the distribution of the daily dose, the duration of treatment and discontinuation of Ethosuximide Medley are determined by a specialist with experience in the treatment of epilepsy.

If you take more Ethosuximide Medley than you should
If by mistake you have taken a double dose of Ethosuximide Medley, do not change your dosage regimen, but continue taking Ethosuximide Medley as prescribed. Significantly higher doses increase effects such as tiredness, lethargy (lack of drive, apathy), depressive states and states of agitation, in some cases also irritability as well as any other side effects depending on the quantity taken (overdose effects may occur at concentrations over 150 microgram ethosuximide per ml blood).

Overdose symptoms are increased by alcohol and other CNS depressants.

If any of these symptoms occur, contact the nearest doctor and, if possible, present the medicine taken and the package leaflet.

If a significant overdose was taken, the doctor will perform gastric lavage and administer medicinal charcoal. Monitoring of the cardiovascular and respiratory systems in an intensive care unit is required.

If you forget to take Ethosuximide Medley
Do not take a double dose to make up for the forgotten dose.
Normally no symptoms will appear when you forgot to take a single dose. Continue taking the medicine as prescribed. Do not take the forgotten dose later. Ethosuximide Medley will control your state safely and appropriately only when you take it regularly.

If you stop taking Ethosuximide Medley
If you wish to discontinue the treatment, talk to your doctor first. Do not stop taking the medicine without checking with your doctor, as this may jeopardise the success of the treatment.
Strictly follow the treatment recommendations of your doctor, as otherwise you may again have epileptic fits.
Tell your doctor if you think that you do not tolerate Ethosuximide Medley.

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 Medley 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)).

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

Other possible side effects
Very common (may affect more than 1 in 10 people):
- Nausea, vomiting, hiccup and abdominal pain

Uncommon (may affect up to 1 in 100 people):
- Severe headache, sleep disturbances, lethargy (lack of drive, apathy), ataxia (movement disorders)
- Withdrawal, anxiety
- Loss of appetite, loss of weight
- Diarrhoea, constipation

Rare (may affect up to 1 in 1000 people):
- Paranoid and hallucinatory phenomena developing over days and weeks (illusion, persecution complex)
- Lupus erythematodes* of varying extent (skin disease that may involve internal organs)
- Leucopenia* (shortage of white blood cells), eosinophilia* (increase of a certain type of white blood cells), thrombocytopenia* (shortage of blood platelets) or agranulocytosis* (absence of certain defensive cells)

Not known (frequency cannot be estimated from the available data):
- In individual cases dyskinesias (movement disorders, see section 2) may occur during the first 12 hours of the treatment.
- Allergic skin reactions* such as rash, Stevens-Johnson syndrome (very severe allergic skin reaction)
- In individual cases aplastic anaemia* (shortage of red blood cells due to failure of body to produce new cells) and pancytopenia* (shortage of all blood cells) may occur (see section 2).

***Side effects which are independent of the dose of the medicine**
If side effects occur which are independent of the dose taken the medicine is usually discontinued and the side effects disappear. They may reappear when Ethosuximide Medley is taken again.

Note:
Long-term treatment may affect the patient's performance, for example, the performance in school of children and adolescents.
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 Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in 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 Medley

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

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

This medicine does not require any special storage condition.

After first opening, use within 3 months.

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 Medley contains
- The active ingredient is ethosuximide. Each 5ml oral solution contains 250 milligram of the active ingredient ethosuximide.
- The other ingredients are sodium citrate (E331), citric acid monohydrate (E330), glycerol (E422), sucrose, raspberry flavour (contains propylene glycol (E1520)), saccharin sodium (E954) and purified water.

What Ethosuximide Medley looks like and contents of the pack
Ethosuximide Medley is a clear colorless to slightly yellowish solution and free from foreign particulate matter. Amber coloured glass bottle with a child-resistant and tampered evident screw cap.
Packs with 125 ml, 200 ml and 250 ml (2 x 125 ml) oral solution in a carton containing a 10 ml graduated syringe marked with graduations of 1 ml, 1.25 ml, 1.5 ml, 1.75 ml, 2 ml,……up to 10 ml. The syringe is made up of a polypropylene (PP) barrel and linear low-density polyethylene (LLDPE) plunger with a linear low-density polyethylene (LLDPE) adaptor for the syringe.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Medley Pharma Limited Unit 2A, Olympic Way, Sefton Business Park, Bootle, Merseyside,
L30 1RD, United Kingdom.

This leaflet was last revised in 06/2024.

Other sources of information

To request a copy of this leaflet in large print, Braille or CD, please call +441515214527

Please be ready to give the following information:

Product Name	Reference Number
Ethosuximide Medley 250 mg/5 ml Oral Solution	PL 43870/0049

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