Package leaflet: Information for the patient

Ethosuximide G.L. Pharma 250 mg/5 ml oral solution sugar free

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 G.L. Pharma is and what it is used for

Ethosuximide G.L. Pharma is a medicine for the treatment of epileptic fits (antiepileptic).

Ethosuximide G.L. Pharma 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 G.L. Pharma

Do not take Ethosuximide G.L. Pharma
- 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 G.L. Pharma.

If you experience movement disorders (see section 4), do not continue taking ethosuximide. 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 haemorrhagic 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 discontinued completely. The liver enzymes should also be checked regularly.

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

A small number of patients treated with antiepileptics 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.

Note:
To prevent grand mals, which are often associated with complex and atypical absences, ethosuximide can be combined with effective antiepileptics (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.

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

Other medicines and Ethosuximide G.L.
Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

What other medicines affect the efficacy of ethosuximide?
In patients also taking carbamazepine (medicine for the treatment of epileptic fits), the plasma clearance (excretion rate) of the active substance ethosuximide, may be elevated. In patients taking valproic acid (medicine for the treatment of epileptic fits), the concentration of ethosuximide in blood may rise.
It cannot be excluded that CNS depressants and ethosuximide mutually potentiate their sedative (calming and sleep inducing) effects.

The efficacy of what other medicines is affected by ethosuximide?
Ethosuximide normally does not change the concentration of other medicines for the treatment of epileptic fits (e.g. primidone, phenobarbital, phenytoin) in blood. In individual cases the phenytoin level in blood may rise, however.

Ethosuximide G.L. Pharma with alcohol
Alcohol can change and potentiate the effects of ethosuximide in an unforeseeable manner. Do not drink alcohol or consume alcohol-containing food while you take ethosuximide!

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 treatment with ethosuximide. Do not discontinue ethosuximide 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 antiepileptic, and therefore combination treatment should be avoided during pregnancy.
Prenatal diagnostic measures like high level ultrasound and the determination of α-fetoprotein are recommended for the early detection of foetal damage.
The lowest effective ethosuximide dose ensuring seizure control must not be exceeded, particularly during 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 a 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
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.

Driving and using machines
Ethosuximide can impair reactivity.
Therefore, the following should be considered throughout the treatment period, in particular, however, 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 G.L. Pharma contains methyl parahydroxybenzoate (E 218),
which may cause allergic reactions, possibly delayed.

Ethosuximide G.L. Pharma contains sodium
Ethosuximide G.L. Pharma contains less than 1 mmol (23 mg) sodium per ml, i.e. it is essentially ‘sodium-free’.

3. How to take Ethosuximide G.L. Pharma

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 µg/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, however.
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 and increasing them gradually to optimum amounts (increasing the amounts slowly from day to day) and by taking them during or after meals.

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.

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.

Children between 2 and 6 years:
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/kg/day. The maximum daily dose is 1000 mg (20 ml).

Method of administration
Oral use
The solution can be taken during or after meals.

Instructions for using the oral syringe
The bottle has a child resistant closure. To remove the child resistant closure, push it down and turn it counter clockwise (see Figure 1). Remove the closure.

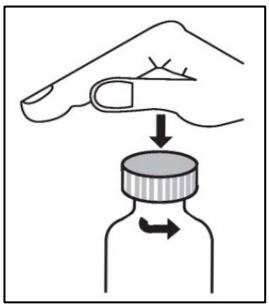

Figure 1

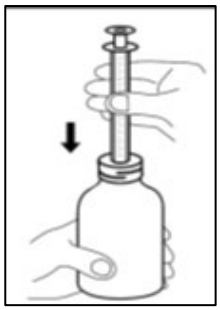

Figure 2

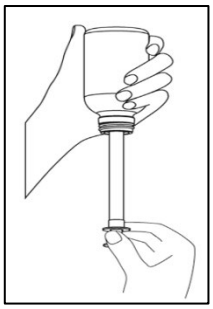

Figure 3

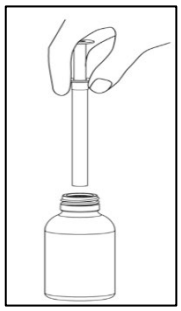

Figure 4

- Place the bottle on a firm and flat surface.
- Push the syringe plunger to the bottom of the barrel of the syringe (toward its tip) to remove excess air.
- Keep the bottle in an upright position and insert the oral syringe firmly into the hole of the adaptor on the bottle (see Figure 2).
- Carefully turn the bottle upside down with the oral syringe firmly in place (see Figure 3).
- In order to withdraw the prescribed dose (mL), pull the plunger back slowly until the top edge of the syringe is exactly level with the line marking the required dose.
- If you see air bubbles in the oral syringe, fully push in the plunger so that the solution flows back into the bottle.
- Turn the bottle to an upright position again. Disconnect the oral syringe by gently twisting it out of the bottle adaptor (see Figure 4).

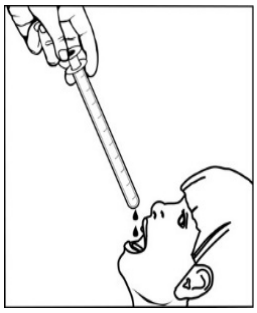

Figure 5

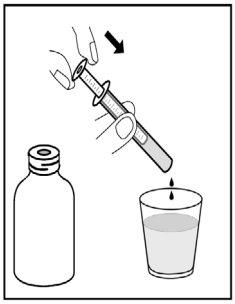

Figure 6

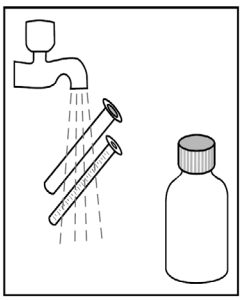

Figure 7

- Take your medicine by placing the oral syringe into your mouth and gently pressing the plunger to the bottom of the syringe barrel to ensure all solution is used (see Figure 5).
- If you prefer, you can dilute the medicine in a glass of water or a non-alcoholic drink before you take it (see Figure 6). In this case drink the whole glass to ensure that you have taken the correct dose of medicine.
- Immediately screw the child resistant closure onto the bottle. The adapter remains in place.
- Clean the oral syringe immediately after use with water. Separate barrel and plunger and rinse both with water (see Figure 7). Shake off excess water and leave the disassembled oral syringe to dry until it is required for the next dose.

<u>How long to take Ethosuximide G.L. Pharma</u>
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 are determined by a specialist with experience in the treatment of epilepsy.

If you take more Ethosuximide G.L. Pharma than you should
If by mistake you have taken a double dose ethosuximide, do not change your dosage regimen, but continue taking ethosuximide as prescribed.
Significantly higher doses potentiate 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 µg ethosuximide per ml blood).
Overdose symptoms are potentiated 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 G.L. Pharma
Do not take a double dose to make up for a forgotten dose. Normally no symptoms will appear when you forgot to take a single dose. Continue taking the medicine as prescribed, i.e. do not take the forgotten dose at a later time. Be advised, however, that ethosuximide will control your state safely and appropriately only when taken regularly!

If you stop taking Ethosuximide G.L. Pharma
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 have again epileptic fits! If you think that you do not tolerate ethosuximide, please contact your doctor!

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.

Serious side effects

Stop using Ethosuximide G.L. Pharma 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 higher 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 side effects

Common (may affect up to 1 in 10 people) to very common (may affect more than 1 in 10 people)
- Nausea, vomiting, hiccups, abdominal pain

Uncommon: may affect up to 1 in 100 people
- Severe headaches, 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 1,000 people
- Paranoid and hallucinatory phenomena developing over days and weeks (illusion, persecution complex)
- Lupus erythematosus* 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) or DRESS (drug reaction with eosinophilia and systemic symptoms)
- 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 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 is taken again.

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 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 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 G.L. Pharma

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 carton and the bottle after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require special storage conditions.

After first opening, use within 6 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 G.L. Pharma contains
- The active substance is ethosuximide. 1 ml oral solution contains 50 mg ethosuximide.
- The other ingredients are: methyl parahydroxybenzoate (E 218), macrogol 300, hypromellose type, sucralose , sodium citrate dihydrate, citric acid monohydrate , purified water.

What Ethosuximide G.L. Pharma looks like and contents of the pack
Oral solution
A clear, slightly viscous, colourless liquid in an amber glass bottle with child-resistant closure and an adapter for the oral syringe.

A carton contains a bottle of 125 ml, 200 ml, or 250 ml solution, a 10 ml graduated oral syringe, graduated in 0.5 ml steps.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
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