Package leaflet: Information for patients

Ethosuximide Aristo 250 mg soft capsules
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. 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 Aristo is and what it is used for

Ethosuximide Aristo is a medicine for the treatment of epileptic fits (anti-epileptic), specifically the following:

- Pyknoleptic absences and complex and atypical absences.
- Myoclonic-astatic petit mal and myoclonic fits in 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 Aristo

Do not take Ethosuximide Aristo
- if you are allergic to ethosuximide, other succinimides (the 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 Aristo.

If you experience movement disorders (see section 4), stop taking Ethosuximide Aristo. Please contact the nearest doctor who may administer intravenous diphenhydramine.

Look out for symptoms of bone marrow depression such as fever, inflammation of the throat, pharynx or tonsils as well as a tendency to bruise easily. Consult your doctor if you experience any of these symptoms.
Your blood count should be checked regularly (initially monthly for one year, then six monthly) to identify potential injury to the medulla. At a leucocyte count (number of white blood cells) of less than 3500/mm³ or a granulocyte ratio of less than 25%, the dose should be reduced or Ethosuximide Aristo discontinued completely. Liver enzyme levels should also be checked regularly.

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

A small number of patients treated with anti-epileptics such as ethosuximide have developed thoughts of self-harm or suicidal thoughts. If at any time during the treatment you have such thoughts, tell your doctor immediately.

Note:
To prevent grand mal fits which are often associated with complex and atypical absences, ethosuximide can be combined with other anti-epileptics (e.g. primidone or phenobarbital). Additional grand mal prophylactic treatment is not needed 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 using Ethosuximide Aristo and seek medical attention immediately if you notice any of the symptoms described in section 4.

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

What other medicines affect Ethosuximide Aristo?
In patients also taking carbamazepine (another anti-epileptic medicine), the plasma clearance (excretion rate) of ethosuximide may be increased.
In patients taking sodium valproate (another anti-epileptic medicine), the blood concentration of ethosuximide may rise.
Taking CNS depressants with Ethosuximide Aristo may increase the sedative (calming and sleep inducing) effects of both medicines.

What other medicines are affected by Ethosuximide Aristo?
Ethosuximide does not normally change the blood concentrations of other anti-epileptic medicines (e.g. primidone, phenobarbital, phenytoin). However, in individual cases, the blood levels of phenytoin may rise.

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

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, your doctor will advise you regarding the need for planning and monitoring any pregnancy before starting treatment with Ethosuximide Aristo. Do not stop taking Ethosuximide Aristo without first consulting your doctor, as epileptic seizures (fits) might recur, which could harm you and/or your unborn child.

No specific malformations of babies are known which were caused by treatment with ethosuximide. However, patients treated with anti-epileptic medicines 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 diagnostic measures such as high level ultrasound and the determination of α-fetoprotein are recommended for the early detection of damage to the foetus.

The lowest effective dose that ensures 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 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 Aristo.

Driving and using machines
Ethosuximide Aristo can impair your ability to react. Therefore, the following should be considered throughout the treatment period, and in particular, during the dose-adjustment phase:
If 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 by your doctor considering how you respond to this medicine. Please note that alcohol further impairs your driving ability.

Ethosuximide Aristo contains sorbitol (E 420)
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Ethosuximide Aristo

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
Treatment is started at a low daily dose of 500 mg (2 capsules). Depending on the patient's tolerance, the dose is increased every five to seven days in increments of max. 250 mg until the fits are controlled by a daily dose of 1000-1500 mg (4-6 capsules). In some cases, a daily dose of 2000 mg (8 capsules), taken in several single doses, may be required.

The risk of side effects can be reduced by taking small initial doses of Ethosuximide Aristo and increasing the dose gradually to optimum amounts (increasing the amounts slowly from day to day) and by taking them during or after meals.

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.
The decision about changes to the dosage regimen can be taken by your doctor only.

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
Children aged 0 to 6 and patients who cannot swallow soft capsules should take ethosuximide as an oral solution. ´The dosage for older children over 6 years is the same as for adults (see beginning of section 3.).

Method of administration
Ethosuximide Aristo is for oral use.
The soft capsules can be taken during or after meals with half a glass of water.

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

If you take more Ethosuximide Aristo than you should
If you have taken a double dose of Ethosuximide Aristo by mistake, do not change your dosage regimen but continue taking Ethosuximide Aristo as prescribed. Significantly higher doses increase side effects such as tiredness, lethargy (lack of drive, apathy), depression and 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 increased by alcohol and other CNS depressants.

If any of these symptoms occur, contact the nearest doctor and, if possible, take the medicine and the package leaflet with you.

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 Aristo
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, i.e. do not take the forgotten dose at a later time.
Ethosuximide Aristo will control your epilepsy safely and appropriately only when taken regularly.

If you stop taking Ethosuximide Aristo
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, otherwise you may have epileptic fits again. If you think that you do not tolerate Ethosuximide Aristo, 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 too, although not everybody gets them.

Serious side effects

Stop using Ethosuximide Aristo 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
- joint pain, skin rashes, fever and kidney problems (systemic lupus erythematosus)
- mental illness causing severe suspiciousness (paranoia)
- seeing, feeling or hearing things that are not there (hallucinations)

Other side effects:

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

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

Rare (may affect up to 1 in 1000 patients):
- Increase in a certain type of white blood cells (eosinophilia)

Not known (frequency cannot be estimated from the available data):
- In individual cases, movement disorders (see section 2) may occur during the first 12 hours of treatment.

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 Aristo is taken again.

The risk of side effects which depend on the dose taken can be reduced by taking small initial doses of Ethosuximide Aristo and increasing them gradually to optimum amounts (increasing the amounts slowly from day to day) and by taking them during or after meals.

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 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 Aristo

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 label and the carton after "Expiry:"/"EXP.". The expiry date refers to the last day of that month.

Do not store above 30 °C.

Do not throw away any medicines via wastewater. 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 Aristo contains
The active substance is Ethosuximide.
Each soft capsule contains 250 mg ethosuximide.

The other ingredients are: Macrogol 300, Gelatin, Glycerol, Sorbitol liquid (partially dehydrated), Purified water, Titanium dioxide (E 171), Iron oxide yellow (E 172).

What Ethosuximide Aristo looks like and contents of the pack
Ethosuximide Aristo 250 mg soft capsules are oval, yellow and opaque soft capsules.
They are packed in PVC/PVdC/Al blisters.
Pack sizes: 50, 56, 100, 200 soft capsules
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Aristo Pharma GmbH
Wallenroder Straße 8-10
13435 Berlin
Germany

ARISTO

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