Package leaflet: Information for patients

Ethosuximide Aristo 250 mg soft capsules

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 Aristo is and what it is used for
2. What you need to know before you take Ethosuximide Aristo
3. How to take Ethosuximide Aristo
4. Possible side effects
5. How to store Ethosuximide Aristo
6. Contents of the pack and other information

1. What Ethosuximide Aristo is and what it is used for

Ethosuximide Aristo contains the active substance ethosuximide which is one of a group of medicines called anti-epileptic drugs. These medicines are used to treat **epilepsy**.

Ethosuximide Aristo 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).

You should consult your doctor if you are unsure why you have been given Ethosuximide Aristo, if you do not feel better or if you feel worse.

2. What you need to know before you take Ethosuximide Aristo

Do not take Ethosuximide Aristo
- if you are allergic to ethosuximide or any of the other ingredients of this medicine (listed in section 6).
- if you have porphyria (a metabolism disorder which causes abdominal pain and mental disorder).

If any of the above apply to you, speak to your doctor or pharmacist.

Warnings and precautions
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. These symptoms often occur within 28 days of starting this medicine, but can happen later.

Talk to your doctor or pharmacist before taking Ethosuximide Aristo if you suffer from or have suffered in the past from any of the following conditions:
- Liver disease.
- Kidney disease.
- 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.

Pay special attention to 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. Your liver enzyme levels 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.

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, tell your doctor immediately.

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

Some medicines may be affected by ethosuximide or they may affect how well ethosuximide will work. Tell your doctor or pharmacist if you are taking:
- isoniazid, a medicine used for certain types of infections
- other medicines used for epilepsy, in particular carbamazepine, phenytoin, sodium valproate and valproic acid. If Ethosuximide Aristo is to replace your other medicines for epilepsy, your doctor will withdraw these gradually to avoid seizures.

Your doctor may need to test the amount of these medicines in your blood to help decide if any of these medicines are affecting your treatment.

Ethosuximide Aristo with food and drink
Ethosuximide Aristo can be taken before or after food and drink.

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.

You should not take this medicine if you are breast-feeding.

Driving and using machines
Ethosuximide Aristo may cause dizziness or drowsiness. If you experience these symptoms, do not drive or use any tools or machinery.

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. Your doctor will decide on the appropriate dose to suit your condition. Check with your doctor or pharmacist if you are not sure.

- It is important to take the medicine at the right time and regularly, as directed by your doctor.
- Swallow the capsules whole with a drink of water.
- Take the capsules with or without food, whichever you prefer.

Recommended dose

Adults, elderly and children over 6 years of age
The usual starting dose is 2 capsules a day.
Your doctor may increase your dose by 1 capsule a day every 5 to 7 days until your epilepsy is well controlled.
A maximum dose of 8 capsules a day, taken in divided doses, may occasionally be necessary.
Do NOT change the dose yourself.

Use in children under 6 years
Children under 6 years and those unable to swallow capsules should take ethosuximide in liquid form.

Blood tests may be carried out to check the level of ethosuximide in your body.

If you take more Ethosuximide Aristo than you should
If you take more capsules than you should, you may feel very drowsy or confused.
1. Tell your doctor, pharmacist or nearest hospital casualty department immediately.
2. Take the bottle and any remaining capsules with you so that people can see what you have taken.
3. Do this even if you feel well.

If you forget to take Ethosuximide Aristo
If you forget to take a dose take it as soon as you remember, but if it is almost time for your next dose skip the forgotten dose and continue as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Ethosuximide Aristo
Do not stop taking the medicine unless your doctor tells you to.
If you suddenly stop taking this medicine you may have a seizure. Should you need to stop taking it, your doctor will decide which method is best for you. Ethosuximide Aristo helps to control your condition but does not cure it. Therefore, you must take your medicine every day, even if you feel well. Do not let yourself run out of medicine, especially over the weekends or on holidays.

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 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 the 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)). 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:

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, 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, shortage of blood cells.

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, 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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