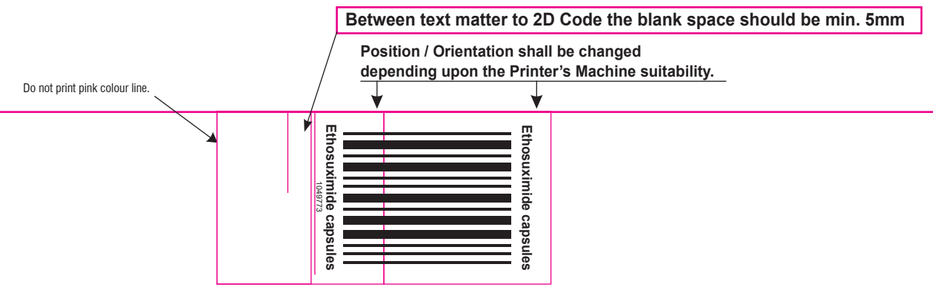

Package leaflet: Information for the user

Ethosuximide 250 mg capsules, soft

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 capsules are and what they are used for

Ethosuximide capsules belongs to a group of medicines called anti-epileptic agents. It is used in a specific form of epilepsy: absence seizures. This is a form of epilepsy with short periods of absence.

This medicine is used to control brief, sudden loss of consciousness (absence seizures, also called petit mal), uncontrolled jerking movements (myoclonic seizures).

Exactly how ethosuximide works is unclear. It can be combined with other medicines for epilepsy.

2 What you need to know before you take Ethosuximide capsules

Do not take Ethosuximide capsules:

- if you are allergic to ethosuximide, other succinimides, lecithin (soya lecithin) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Ethosuximide capsules:

- if you have a liver or kidney function disorder,
- if you various from of epilepsy. In this case, ethosuximide may trigger generalised seizures (seizures spread over the whole the body),
- if you have decreased bone marrow function or reduced platelet count in your blood,
- Severe skin reactions have been reported including Stevens-Johnson syndrome and drug reaction with eosinophilia and systemic symptoms (DRESS) during Ethosuximide capsules treatment. Stop using this medicine and seek medical help immediately if you notice any of the symptoms described in section 4.

A small number of people treated with anti-epileptic medicines such as Ethosuximide capsules have also had thoughts of self-harm or suicide. If you have these thoughts at any time, contact your doctor immediately.

Pay special attention to symptoms that indicate that your body is producing too few blood cells (bone marrow depression) such as fever, inflammation of the throat or tonsils and tendency to bleed more easily, and consult your doctor if you experience any of these symptoms.

Your blood must be checked regularly (initially monthly and after a year every six months). Your liver enzymes must also be checked regularly.

Other medicines and Ethosuximide capsules

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

- Medicines known to influence the effect of ethosuximide or which may be influenced by the effect of ethosuximide are: other medicines for epilepsy (phenytoin, valproic acid);
- isoniazid (medicine for tuberculosis). The amount of ethosuximide in your blood may be increased;
- sedatives that affect the nervous system.

Ethosuximide capsules with alcohol

Simultaneous use of alcohol may have an adverse effect on the nervous system. The use of alcohol is therefore not advised.

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 for advice before taking this medicine.

Women of childbearing potential

In case you are able to get pregnant your doctor will advise you to plan and monitor your pregnancy before starting the treatment with Ethosuximide Strides. Do not suddenly stop using this medicine since it may lead to breakthrough seizures that could harm you or your unborn child. Tell your doctor immediately if you are pregnant, think you may be pregnant or are trying for a baby.

Pregnancy

It is unclear whether the use of ethosuximide during pregnancy may be harmful. In animal studies ethosuximide was shown to be harmful. When using other medicines to treat epileptic seizures, an increased risk of harm to the foetus has been reported, especially if more than one anti-epileptic medicine was taken at the same time. For this reason, if possible, and only following consultation with your doctor, you should take only one anti-epileptic medicine during pregnancy.

Do not stop using this medicine suddenly. This may lead to breakthrough seizures which may have serious consequences for you and your child. Tell your doctor immediately if you are pregnant, think you may be pregnant or are planning to have a baby. The risk of using ethosuximide must be weighed against the risk of seizures during pregnancy.

Breast-feeding

Ethosuximide passes into breast milk.

Side effects may occur in the baby, such as irritability, difficulty feeding and drowsiness. Breast-feeding during ethosuximide treatment not recommended.

Driving and using machines

Ethosuximide may cause drowsiness and dizziness as side effects. This must be borne in mind when driving or using potentially hazardous machinery.

Therefore, the following should be considered throughout the treatment period and especially during any adjustments of dosage: you may 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 and do not work or perform any hazardous tasks without a secure hold.

Ethosuximide capsules contains sorbitol and lecithin (soya lecithin)

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. This medicine contains 36 mg sorbitol in each capsule.

This medicine contains lecithin (soya lecithin). If you are allergic to soya, do not use this medicinal product.

3. How to take Ethosuximide capsules

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

The recommended dose for adults and children over the age of 6 years is: start with 250 mg twice daily.

400 x 340 mm

FRONT SIDE

10839

ARTWORK DETAIL LABEL

NON PRINTING COLOUR

Product	**Ethosuximide 250 mg soft capsules**				
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert		
Dimension	**400 x 340 mm**			Pack	----
New Item Code	**1049773**	Old Item Code	1048852		
Colour Shades	Black			No. of Colours	1

Change Control No.	PC-ODF/2023/613 - Record Number: 398658	Artwork Version	7.0
Design/Style	Front & Back Printing. Booklet Form. (Folded size: 31 x 30 mm). To be supplied in the folded Booklet form with pasting.		
Substrate	40/45 GSM Paper		
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.		
Autocartonator Requirements	NA		

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. **DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.**

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For children aged 3 to 6 years: start with 250 mg once daily.

For children younger than 3 years: start with 10 mg/kg body weight per day divided between 1-2 doses. After this, the dosage is 20-40 mg/kg body weight per day in 1-2 doses.

The dosage may be increased by 125 mg every 4-7 days until the right dosage is reached; the maximum dosage for adults and children over the age of 6 years is 1.5-2 g.

For children under the age of 6 years, the maximum dosage is 1 g.

For different dosages, uses other pharmaceutical form is available on the market.

The capsules must be swallowed whole with plenty (half a glass) of water.

If you take more Ethosuximide capsules than you should

If too much has been taken, nausea, vomiting, headache, dizziness, reduced appetite, coordination disturbances, tremor, restlessness (of muscles), involuntary movements, central nervous system depression (leading to coma), reduced blood pressure (characterised by light-headedness), difficulty breathing, hypersensitivity reactions such as skin reactions, behavioural changes and delusions may occur.

If you suspect an overdose, you must tell a doctor immediately,

If you forget to take Ethosuximide capsules

If you have forgotten to take a dose take it as soon as possible, unless it is almost time for the next dose. Never take a double dose to make up for a forgotten dose.

If you stop taking Ethosuximide capsules

Never stop taking the treatment of your own accord. Use of ethosuximide capsules must be discontinued gradually and under the supervision your doctor.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The use of ethosuximide may lead to the following side effects: gastrointestinal symptoms, headache, dizziness, drowsiness, behavioural disturbances, mental disturbances (sometimes in the form of delusions) and (rarely) changes in composition of the blood.

In rare cases, blood abnormalities (abnormal red or white cell count) and severe skin reactions may occur.

Some side effects occur somewhat more often if ethosuximide is combined with other medicines for epilepsy.

Severe side effects

STOP taking the capsules and seek medical help immediately if you have any of the following allergic reactions:

- Reddish patches on the trunk, appearing as rings or round spots, often with central blisters, skin peeling, ulcers of the mouth, throat, nose, genitals or eyes. This severe skin rashes may 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 immediate medical attention if you have any of the following symptoms:

Not known (frequency cannot be estimated from the available data):

- Changes to your blood (bruising more easily or bleeding, fever, sore throat, mouth ulcers, tiredness or repeated or persistent infections). Your doctor may take regular blood samples to test for these effects.

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 capsules

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

Store the capsules in the original package in a dry place, below 25°C.

The medicine should be consumed within 60 days after its first opening.

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 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 capsule contains

- The active substance is ethosuximide. Each capsule contains 250 mg of ethosuximide.
- The other ingredients are: macrogol; for capsule shells - gelatin, glycerol, liquid sorbitol (E420) (non-crystallising), erythrosine (E 127) (FD & C Red #3), purified water, macrogol, medium chain triglyceride, lecithin.

What Ethosuximide capsule looks like and contents of the pack

Ethosuximide capsules are red coloured, oblong shaped soft gelatin capsules containing colourless to red colour viscous liquid.

Capsule dimensions: 19 mm in length and 8 mm in width.

The capsules are available in a bottle pack consisting of a high density polyethylene container with outer white opaque polypropylene child resistant closure.

Pack sizes: 28, 56, 100 and 112 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Strides Pharma UK Ltd.
Unit 4, The Metro Centre,
Dwight Road, Watford
WD18 9SS
United Kingdom

This leaflet was last revised in 02/2024.

1049773
PL 13606/0208

400 x 340 mm

BACK SIDE

NON PRINTING COLOUR

ARTWORK DETAIL LABEL

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