

PACKAGE LEAFLET

Package leaflet: Information for the patient
Ethosuximide Tillomed 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 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

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1. What Ethosuximide Tillomed capsules are and what they are used for

The full name of your medicine is Ethosuximide Tillomed 250 mg Soft Capsules. They are referred to as Ethosuximide Tillomed capsules throughout this leaflet. Ethosuximide Tillomed capsules contain ethosuximide which belongs to a group of medicines known as anticonvulsant agents. It is used to control epilepsy in children and adults. Epilepsy is a condition where you have repeated seizures (fits). This medicine is used to control brief, sudden loss of consciousness (absence seizures, also called petit mal) and uncontrolled jerking movements (myoclonic seizures).

How ethosuximide works exactly is unclear. It can be combined with other medicines for epilepsy.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take Ethosuximide Tillomed capsules

Do not take Ethosuximide Tillomed capsules:

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

Talk to your doctor or pharmacist before taking Ethosuximide Tillomed capsules.

- if you have liver or kidney problems;
- if you are pregnant or planning a pregnancy, or if you are breast-feeding;

- if you suffer from a different form of epilepsy. In this case, ethosuximide may trigger generalised seizures (seizures spread throughout the body);
- if you have bone marrow depression (decreased number of certain cells in the bone marrow) or a low blood platelet count;
- if you are taking isoniazid, a medicine used for certain types of infections
- 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 Tillomed capsules and seek medical attention immediately if you notice any of the symptoms described in section 4.**

Pay special attention to symptoms of bone marrow depression such as fever, inflammation of throat or pharynx tonsils as well as haemorrhagic tendency (a tendency to bleed easily which can occur in conditions such as low platelet count, liver disease, kidney failure, anticoagulant therapy) and consult your doctor, if you experience any of these symptoms.

Your blood count should be checked regularly (initially monthly, after one year every six months) to identify potential injury of the bone marrow (inner part of the bone where blood cells are formed). Your liver enzymes should also be checked regularly.

A small number of people treated with anticonvulsant agents such as ethosuximide have also had thoughts about self-harm or suicide. If you have such thoughts at any time, contact your doctor immediately.

If you experience movement disorders (see section 4) do not continue taking Ethosuximide Tillomed Capsules. Please, contact the nearest doctor who, in the event of significant disturbances, can administer diphenhydramine as an antidote, if required.

Other medicines and Ethosuximide Tillomed capsules

Tell your doctor or pharmacist if you are taking, or have recently used or might take any other medicines, including medicines obtained without a prescription.

In particular, inform your doctor if you are taking any of the following medicines known to affect the way ethosuximide works or known to be affected by ethosuximide:

- other medicines for epilepsy (carbamazepine, primidone, lamotrigine, phenobarbital, phenytoin, valproic acid);
- isoniazid (medicine for tuberculosis). The amount of ethosuximide in the blood may be increased;
- sedatives that affect the nervous system.

Ethosuximide Tillomed capsules with alcohol

If used at the same time, alcohol may have an adverse effect on the nervous system. The use of alcohol is therefore not recommended.

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.

Pregnancy

It is not clear whether the use of ethosuximide during pregnancy may be harmful. Ethosuximide has been shown to be harmful in animal trials. An increased risk of harm to the foetus has been reported with use of other medicines to treat epileptic seizures, especially when more than one medicine for epileptic seizures is used at the same time. Hence wherever possible, you should use only one medicine for epileptic seizures during pregnancy and only after consultation with your doctor.

Do not suddenly stop using this medicine. This may lead to breakthrough seizures that could have serious consequences for you and your child. Tell your doctor immediately if you are pregnant, think you may be pregnant or are trying for 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 infant, such as irritability, poor sucking reflex and drowsiness. Breast feeding during treatment with Ethosuximide Tillomed capsules is therefore not recommended.

Driving and using machines

Ethosuximide can impair a patient's reactivity and ability to react speedily and may cause side effects such as drowsiness or dizziness.

Therefore, the following should be considered throughout the treatment period and especially during any adjustments of dosage: you may not be 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.

The decision about whether you can 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 capability.

Ethosuximide Tillomed capsules contain sorbitol

This medicine contains 17.43 mg sorbitol in each capsule.

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.

3. How to take Ethosuximide Tillomed capsules

Always take this medicine exactly as your doctor has told you and always read the label.

Your doctor will decide on the appropriate dose to suit your condition. Check with your doctor 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.

Doses

Adults, elderly and children over 6 years:

the usual starting dose is 2 capsules a day.

Your doctor may increase your dose by 250 mg (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.

The risk of side effects which depend on the dose taken can be reduced by taking small initial doses of Ethosuximide Tillomed capsules 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 children under 6 years

Children under 6 years and those who are unable to swallow capsules will be given ethosuximide in liquid form.

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

Ethosuximide syrup is available for different dosages.

If you take more Ethosuximide Tillomed capsules 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 container and any remaining capsules with you so that people can see what you have taken.

Do this even if you feel well.

If you forget to take Ethosuximide Tillomed capsules

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 missed dose and continue as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Ethosuximide Tillomed capsules

Stopping this medicine suddenly may make your seizures worse. The doctor will advise you how to stop the medicine gradually. Keep taking this medicine for as long as the doctor tells you to. Ethosuximide 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 weekend or on holidays. If you have any further questions on taking this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
 - severe itching of the skin, with a red rash or raised lumps
 - blistering of the mouth, eyes, and genital region, and patchy areas of rash, peeling skin
 - 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 immediate medical attention if you have any of the following symptoms:

- fever, sore throat, mouth ulcers, bruising or bleeding, repeated infections or infections that will not go away. This may be due to changes in your blood. Blood tests may be carried out to test for this.
- increased seizures (fits). Blood tests may be carried out and your doctor may adjust the dose.
- fever, rash, painful joints, or kidney inflammation (you may not be able to feel this) which is a general reaction affecting many of the body organs, called a Lupus-like reaction reported in children. Your doctor may wish to perform repeated blood or urine tests.

Rare (may affect up to 1 in 1,000 people):

- nephrotic syndrome (a condition in which your kidneys release an excessive amount of protein (proteinuria) in your urine)
- skin rash, erythema nodosum, Stevens-Johnson syndrome
- Systemic lupus erythematosus (SLE)

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

- peripheral blood count abnormalities (slight decrease in leukocytes)
- aplastic anaemia
- agranulocytosis (extremely low number of neutrophils (type of white blood cell) in the blood)
- pancytopenia (low levels of all three blood cell types: red blood cells, white blood cells and platelets)
- neutrophilia (increased neutrophils in blood)
- monocytosis (increased monocytes in the blood)
- eosinophilia (increased eosinophils in the blood)
- leukopenia (decreased white blood cell count)
- states of agitation
- depression
- paranoid psychoses
- sleep disturbances
- increased libido
- apathy
- euphoria
- ataxia (poor muscle control when you have a problem with coordination)
- dyskinesia (uncontrolled, involuntary muscle movements)
- photophobia
- headache
- dizziness
- drowsiness
- anorexia
- behavioural disorders
- fatigue
- hyperactivity
- myopia (difficulty seeing distant objects (-near-sightedness))

- gastrointestinal disorder
- nausea, vomiting
- diarrhoea
- abdominal pain
- gum hypertrophy (excessive growth of the gums)
- swelling of the tongue
- vaginal bleeding
- weight loss
- hiccoughs
- irritability
- night terrors
- inability to concentrate
- aggressiveness
- 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.

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 Tillomed capsules

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

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the label and the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicine you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Ethosuximide Tillomed capsules contain

- The active substance is ethosuximide. Each capsules contains 250 mg of ethosuximide.
- The other ingredients are gelatin, glycerol, sorbitol, macrogol 400, purified water and printing ink (containing shellac glaze ~45%, titanium dioxide, isopropyl alcohol, propylene glycol, N-butyl alcohol, ammonium hydroxide 28%, simethicone)

What Ethosuximide Tillomed capsules looks like and contents of the pack

Ethosuximide capsules are transparent clear, oblong, soft gelatin capsules filled with clear liquid. Imprinted with “HP 532” with White ink.

The soft capsules are available in;

- HDPE bottle pack with a white round plastic (polypropylene) child resistant closure (CRC) cap with liner.
Pack sizes: 56’s, 100’s, 200’s capsules

- PVC/PVDC/Alu Blister Pack in Carton.
Pack sizes: 56’s capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in {April 2024}.