

MEDICATION GUIDE

ETHOSUXIMIDE ORAL SOLUTION, USP, 250 mg/5 mL

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Read this Medication Guide before you start taking ethosuximide oral solution and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. If you have any questions about ethosuximide oral solution, ask your healthcare provider or pharmacist.

What is the most important information I should know about ethosuximide oral solution?

Do not stop taking ethosuximide oral solution without first talking to your healthcare provider.

Stopping ethosuximide oral solution suddenly can cause serious problems.

Ethosuximide oral solution can cause serious side effects, including:

1. Rare but serious blood problems that may be life-threatening. Call your healthcare provider right away if you have:

- fever, swollen glands, or sore throat that come and go or do not go away
- frequent infections or an infection that does not go away
- easy bruising
- red or purple spots on your body
- bleeding gums or nose bleeds
- severe fatigue or weakness

2. Drug reactions that may affect different parts of the body such as your liver, kidneys, heart, or blood cells. You may or may not have a rash with these types of reactions. These reactions can be very serious and can cause death. Call your healthcare provider right away if you have any of these symptoms:

- joint pain and swelling
- muscle pain
- fatigue, weakness
- low-grade fever
- pain in the chest that is worse with breathing
- skin rash
- swollen lymph glands
- swelling of your face
- yellowing of your skin or the white part of your eyes

3. Like other antiepileptic drugs, ethosuximide oral solution may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempts to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.

Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Do not stop ethosuximide oral solution without first talking to a healthcare provider.

- Stopping ethosuximide oral solution suddenly can cause serious problems.
- Stopping a seizure medicine suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus).

Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

What is ethosuximide oral solution?

Ethosuximide oral solution is a prescription medicine used to treat absence (petit mal) seizures.

Who should not take ethosuximide oral solution?

Do not take ethosuximide oral solution if you are allergic to succinimides (methsuximide or ethosuximide), or any of the ingredients in ethosuximide oral solution. See the end of this Medication Guide for a complete list of ingredients in ethosuximide oral solution.

What should I tell my healthcare provider before taking ethosuximide oral solution?

Before you take ethosuximide oral solution, tell your healthcare provider if you:

- have or had liver problems
- have or have had depression, mood problems or suicidal thoughts or behavior
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if ethosuximide oral solution can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking ethosuximide oral solution. You and your healthcare provider should decide if you should take ethosuximide oral solution while you are pregnant.
- are breast-feeding or plan to breast-feed. It is not known if ethosuximide can pass into breast milk. You and your healthcare provider should decide how you will feed your baby while you take ethosuximide oral solution.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Taking ethosuximide oral solution with certain other medicines can cause side effects or affect how well they work. Do not start or stop other medicines without talking to your healthcare provider.

Know the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist when you get a new medicine.

How should I take ethosuximide oral solution?

- Take ethosuximide oral solution exactly as prescribed. Your healthcare provider will tell you how much ethosuximide oral solution to take.
- Your healthcare provider may change your dose. Do not change your dose of ethosuximide oral solution without talking to your healthcare provider.
- If you take too much ethosuximide oral solution, call your healthcare provider or your local Poison Control Center right away.

What should I avoid while taking ethosuximide oral solution?

- Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking ethosuximide oral solution without first talking to your healthcare provider. Ethosuximide oral solution taken with alcohol or medicines that cause sleepiness or dizziness may make your sleepiness or dizziness worse.
 - Do not drive, operate heavy machinery, or do other dangerous activities until you know how ethosuximide oral solution affects you. Ethosuximide oral solution can slow your thinking and motor skills.

What are the possible side effects of ethosuximide oral solution?

- See “What is the most important information I should know about ethosuximide oral solution?”

Ethosuximide oral solution may cause other serious side effects, including:

• Serious allergic reactions. Call your healthcare provider right away if you have any of these symptoms:

- skin rash
- hives
- sores in your mouth
- blistering or peeling skin

• Changes in thinking, mood, or behavior. Some patients may get abnormally suspicious thoughts, hallucinations (seeing or hearing things that are not there), or delusions (false thoughts or beliefs).

• Grand mal seizures can happen more often or become worse

Call your healthcare provider right away, if you have any of the symptoms listed above.

The most common side effects of ethosuximide oral solution include

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| • nausea or vomiting | • fatigue |
| • indigestion, stomach pain | • dizziness or lightheadedness |
| • diarrhea | • unsteadiness when walking |
| • weight loss | • headache |
| • loss of appetite | • loss of concentration |
| • hiccups | |

Tell your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the possible side effects of ethosuximide oral solution.

For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ethosuximide oral solution?

• Store ethosuximide oral solution at 20° to 25°C (68° to 77°F).

Preserve in tight containers. Protect from freezing and light.

Keep ethosuximide oral solution and all medicines out of the reach of children.

General information about ethosuximide oral solution

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ethosuximide oral solution for a condition for which it was not prescribed. Do not give ethosuximide oral solution to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about ethosuximide oral solution. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about ethosuximide oral solution that is written for healthcare professionals.

For more information, call 1-845-232-1683.

What are the ingredients in ethosuximide oral solution?

Active ingredient: ethosuximide

Inactive ingredients: artificial raspberry flavor, citric acid anhydrous, ethyl maltol, FD&C Red No. 40, FD&C Yellow No. 6, glycerin, purified water, saccharin sodium, sodium benzoate, sodium citrate, and sucrose.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured for:

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