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MEDICATION GUIDE

Ethosuximide Capsules, USP

(Etho sux i mide)

Read this Medication Guide before you start taking ethosuximide capsules 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 capsules, ask your healthcare provider or pharmacist.

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

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

Stopping ethosuximide capsules suddenly can cause serious problems.

Ethosuximide capsules 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 capsules 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 capsules without first talking to a healthcare provider.

- Stopping ethosuximide capsules 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 are ethosuximide capsules?

Ethosuximide capsules are prescription medicine used to treat absence (petit mal) seizures.

Who should not take ethosuximide capsules?

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

What should I tell my healthcare provider before taking ethosuximide capsules?

Before you take ethosuximide capsules, 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 capsules can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking ethosuximide capsules. You and your healthcare provider should decide if you should take ethosuximide capsules while you are pregnant.
 - If you become pregnant while taking ethosuximide capsules, talk to your healthcare provider about registering with the North American Antiepileptic Drug (NAAED) Pregnancy Registry. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy. You can enroll in this registry by calling 1-888-233-2334.
- 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 capsules.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Taking ethosuximide capsules 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 capsules?

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

What should I avoid while taking ethosuximide capsules?

- Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking ethosuximide capsules without first talking to your healthcare provider. Ethosuximide capsules 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 capsules affects you. Ethosuximide capsules can slow your thinking and motor skills.

What are the possible side effects of ethosuximide capsules?

- See "What is the most important information I should know about ethosuximide capsules?"

Ethosuximide capsules 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 capsules include

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 with ethosuximide capsules. 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 capsules?

- Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].
- Dispense in a tight container as defined in the USP.

Keep ethosuximide capsules and all medicines out of the reach of children.

General information about ethosuximide capsules

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

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

For more information, go to www.chartwellpharma.com or call 1-845-232-1683.

What are the ingredients in Ethosuximide Capsules, USP?

Active ingredient: Ethosuximide, USP

Capsules Inactive ingredients:

FD&C red # 40 aluminum lake, FD&C yellow # 6 aluminum lake, gelatin, glycerin, light mineral oil, methyl paraben, polyethylene glycol, propyl paraben, and sorbitol. The capsule shell is imprinted with white imprinting ink containing opacode white S-1-7078 as colorant which contains the following inactive ingredients: ammonium hydroxide, isopropyl alcohol, n-butyl alcohol, propylene glycol, shellac glaze, simethicone and titanium dioxide.

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

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