

MEDICATION GUIDE

CELONTIN (Suh lōn' tīn) (methsuximide)

Capsules

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

What is the most important information I should know about CELONTIN?

Do not stop taking CELONTIN without first talking to your healthcare provider. Stopping CELONTIN suddenly can cause serious problems.

CELONTIN 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. Systematic Lupus Erythematosus.** Call your healthcare provider right away if you have any of these symptoms:
 - joint pain and swelling
 - muscle pain
 - fatigue
 - low-grade fever
 - pain in the chest that is worse with breathing
 - unexplained skin rash
- 3. Like other antiepileptic drugs, CELONTIN 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 CELONTIN without first talking to a healthcare provider.

Stopping CELONTIN 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 CELONTIN?

CELONTIN is a prescription medicine used to treat absence (petit mal) seizures that have not gotten better with other seizure medicines.

Who should not take CELONTIN?

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

What should I tell my healthcare provider before taking CELONTIN?

Before you take CELONTIN, tell your healthcare provider if you:

- have or have 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 CELONTIN can harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking CELONTIN. You and your healthcare provider will decide if you should take CELONTIN while you are pregnant.

- If you become pregnant while taking CELONTIN, 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 breastfeeding or plan to breastfeed. It is not known if CELONTIN can pass into breast milk. You and your healthcare provider should decide how you will feed your baby while you take CELONTIN.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Taking CELONTIN 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 each time you get a new medicine.

How should I take CELONTIN?

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

What should I avoid while taking CELONTIN?

- Do not drink alcohol or take other medicines that make you sleepy or dizzy while taking CELONTIN without first discussing this with your healthcare provider. CELONTIN 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 CELONTIN affects you. CELONTIN can slow your thinking and motor skills.

What are the possible side effects of CELONTIN?

- See **“What is the most important information I should know about CELONTIN?”**

CELONTIN may cause other serious side effects, including:

- Grand mal seizures can happen more often or become worse

The most common side effects of CELONTIN include:

- drowsiness
- dizziness
- headache
- blurred vision
- nausea or vomiting
- constipation
- diarrhea
- weight loss
- problems with walking and coordination (unsteadiness)
- stomach pain
- loss of appetite

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 CELONTIN. 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 CELONTIN?

- Store CELONTIN at room temperature, between 59°F to 86°F (15°C to 30°C).
- Keep CELONTIN capsules in a dry place.
- Keep CELONTIN out of the light.
- Protect CELONTIN from heat.
- Do not use CELONTIN capsules that if they do not look full or if the contents have melted.

Keep CELONTIN and all medicines out of the reach of children.

General information about CELONTIN

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

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

For more information, go to www.pfizer.com or call 1-800-438-1985.

What are the ingredients in CELONTIN?

Active ingredient: methsuximide

Inactive ingredients: starch, colloidal silicon dioxide NF, D&C yellow No. 10, FD&C yellow No.6, gelatin NF, and sodium lauryl sulfate NF.

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



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