

MEDICATION GUIDE

Clobazam (KLOE-ba-zam) Tablets, CIV

What is the most important information I should know about Clobazam Tablets?

- **Do not stop taking clobazam tablets without first talking to your healthcare provider.** Stopping clobazam tablets suddenly can cause serious side effects.
- **Clobazam is a benzodiazepine medicine. Benzodiazepines can cause severe drowsiness, breathing problems (respiratory depression), coma, and death when taken with opioid medicines.**
- **Clobazam tablets can make you sleepy or dizzy and can slow your thinking and motor skills. This may get better over time.**
 - Do not drive, operate heavy machinery, or do other dangerous activities until you know how clobazam tablets affects you.
 - Clobazam tablets may cause problems with your coordination, especially when you are walking or picking things up.
- **Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking clobazam tablets until you talk to your healthcare provider.** When taken with alcohol or drugs that cause sleepiness or dizziness, clobazam tablets may make your sleepiness or dizziness much worse.
- **Clobazam tablets can cause withdrawal symptoms.**
 - Do not stop taking clobazam tablets all of a sudden without first talking to a healthcare provider. Stopping clobazam tablets suddenly can cause seizures that will not stop (status epilepticus), hearing or seeing things that are not there (hallucinations), shaking, nervousness, and stomach and muscle cramps.
 - Talk to your healthcare provider about slowly stopping clobazam tablets to avoid withdrawal symptoms.
- **Clobazam tablets can be abused and cause dependence.**
 - Physical dependence is not the same as drug addiction. Your healthcare provider can tell you more about the differences between physical dependence and drug addiction.
- **Clobazam is a federal controlled substance (CIV) because it can be abused or lead to dependence.** Keep clobazam tablets in a safe place to prevent misuse and abuse. Selling or giving away clobazam tablets may harm others, and is against the law. Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.
- **Serious skin reactions have been seen when clobazam tablets are taken with other medicines and may require stopping its use.** Do not stop taking clobazam tablets without first talking to your healthcare provider.
 - A serious skin reaction can happen at any time during your treatment with clobazam tablets, but is more likely to happen within the first 8 weeks of treatment. These skin reactions may need to be treated right away.
 - Call your healthcare provider immediately if you have skin blisters, rash, sores in the mouth, hives or any other allergic reaction.
- **Like other antiepileptic drugs, clobazam tablets may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.**

Call your 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
- new or worse anxiety
- trouble sleeping (insomnia)
- acting on dangerous impulses
- attempts to commit suicide
- feeling agitated or restless
- new or worse irritability
- an extreme increase in activity and talking (mania)
- new or worse depression
- panic attacks
- acting aggressive, being angry, or violent
- 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. 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 clobazam tablets?

Clobazam tablets are a prescription medicine used along with other medicines to treat seizures associated with Lennox-Gastaut syndrome in people 2 years of age or older.

It is not known if clobazam tablets are safe and effective in children less than 2 years old.

Do not take clobazam tablets if you:

- are allergic to clobazam or any of the ingredients in clobazam tablets. See the end of this Medication Guide for a complete list of ingredients in clobazam tablets.

Before you take clobazam tablets, tell your healthcare provider about all your medical conditions, including if you:

- have liver or kidney problems
- have lung problems (respiratory disease)
- have or have had depression, mood problems, or suicidal thoughts or behavior
- use birth control medicine. Clobazam tablets may cause your birth control medicine to be less effective. Talk to your healthcare provider about the best birth control method to use.
- are pregnant or plan to become pregnant. **Clobazam tablets may harm your unborn baby.**
 - Tell your healthcare provider right away if you become pregnant while taking clobazam tablets. You and your healthcare provider will decide if you should take clobazam tablets while you are pregnant.
 - Babies born to mothers receiving benzodiazepine medications (including clobazam tablets) late in pregnancy may be at some risk of experiencing breathing problems, feeding problems, dangerously low body temperature, and withdrawal symptoms.
- If you become pregnant while taking clobazam tablets, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can register by calling 1-888-233-2334. For more information about the registry go to

<http://www.aedpregnancyregistry.org>. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy.

- Clobazam can pass into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take clobazam tablets. You and your healthcare provider should decide if you will take clobazam tablets or breastfeed. You should not do both.

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

How should I take clobazam tablets?

- Take clobazam tablets exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much clobazam tablets to take and when to take it.
- Clobazam tablets can be taken whole, broken in half along the score, or crushed and mixed in applesauce.
- Clobazam tablets can be taken with or without food.
- Your healthcare provider may change your dose if needed. Do not change your dose of clobazam tablets without talking to your healthcare provider.
- Do not stop taking clobazam tablets without first talking to your healthcare provider.
- Stopping clobazam tablets suddenly can cause serious problems.
- If you take too much clobazam tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking clobazam tablets?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how clobazam tablets affect you.
- Do not drink alcohol or take other medicines that may make you sleepy or dizzy while taking clobazam tablets until you talk to your healthcare provider. When taken with alcohol or medicines that cause sleepiness or dizziness, clobazam tablets may make your sleepiness or dizziness much worse.

What are the possible side effects of clobazam tablets?

Clobazam tablets may cause serious side effects, including: See “What is the most important information I should know about clobazam tablets?”

The most common side effects of clobazam tablets include:

- sleepiness
- cough
- acting aggressive, being angry, or violent
- tiredness
- drooling
- pain with urination
- difficulty sleeping
- problems with breathing
- constipation
- fever
- slurred speech

These are not all the possible side effects of clobazam tablets. **Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Lupin Pharmaceuticals, Inc. at 1-800-399-2561.**

How should I store clobazam tablets?

- Store clobazam tablets between 68°F to 77°F (20°C to 25°C).

Tablets

- Keep clobazam tablets in a dry place.
- **Keep clobazam tablets and all medicines out of the reach of children.**

General information about the safe and effective use of clobazam tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use clobazam tablets for a condition for which it was not prescribed. Do not give clobazam tablets to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about clobazam tablets that is written for health professionals.

What are the ingredients in clobazam tablets?

Active ingredient: clobazam

Inactive ingredients: colloidal silicon dioxide, corn starch, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and sodium starch glycolate.

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

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