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MEDICATION GUIDE

Clobazam (KLOE–ba–zam) Tablets, CIV

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

- **Clobazam is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system (CNS) depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.** Get emergency help right away if any of the following happens:
 - shallow or slowed breathing
 - breathing stops (which may lead to the heart stopping)
 - excessive sleepiness (sedation)Do not drive or operate heavy machinery until you know how taking clobazam with opioids affects you.
- **Risk of abuse, misuse, and addiction. There is a risk of abuse, misuse, and addiction with benzodiazepines, including clobazam, which can lead to overdose and serious side effects including coma and death.**
 - **Serious side effects including coma and death have happened in people who have abused or misused benzodiazepines, including clobazam.** These serious side effects may also include delirium, paranoia, suicidal thoughts or actions, seizures, and difficulty breathing. **Call your healthcare provider or go to the nearest hospital emergency room right away if you get any of these serious side effects.**
 - **You can develop an addiction even if you take clobazam as prescribed by your healthcare provider.**
 - **Take clobazam exactly as your healthcare provider prescribed.**
 - Do not share your clobazam with other people.
 - Keep clobazam in a safe place and away from children.
- **Physical dependence and withdrawal reactions.** Clobazam can cause physical dependence and withdrawal reactions.
 - **Do not suddenly stop taking clobazam.** Stopping clobazam suddenly can cause serious and life-threatening side effects, including, unusual movements, responses, or expressions, seizures, sudden and severe mental or nervous system changes, depression, seeing or hearing things that others do not see or hear, an extreme increase in activity or talking, losing touch with reality, and suicidal thoughts or actions. **Call your healthcare provider or go to the nearest hospital emergency room right away if you get any of these symptoms.**
 - **Some people who suddenly stop benzodiazepines have symptoms that can last for several weeks to more than 12 months,** including, anxiety, trouble remembering, learning, or concentrating, depression, problems sleeping, feeling like insects are crawling under your skin, weakness, shaking, muscle twitching, burning or prickling feeling in your hands, arms, legs or feet, and ringing in your ears.
 - 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.
 - Do not take more clobazam than prescribed or take clobazam for longer than prescribed

- **Clobazam tablets can make you sleepy or dizzy and can slow your thinking and motor skills.**
 - Do not drive, operate heavy machinery, or do other dangerous activities until you know how clobazam tablets affects you.
 - Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking clobazam tablets without first talking 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.
- **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.
- **A serious allergic reaction that may affect your skin or other parts of your body such as your liver, kidneys, heart, or blood cells.** This allergic reaction can be life-threatening and can cause death, particularly if it is not treated as early as possible. Call your healthcare provider right away if you have:
 - a skin rash
 - swelling of your face
 - dark urine
 - fever or swollen glands that do not go away
 - shortness of breath
 - yellowing of the skin or whites of the eyes
- **Like other antiepileptic medicines, 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 or irritability
- trouble sleeping (insomnia)
- acting on dangerous impulses
- attempts to commit suicide
- feeling agitated or restless
- new or worse panic attacks
- other unusual changes in behavior or mood
- new or worse depression
- an extreme increase in activity and talking (mania)
- acting aggressive, being angry, or violent

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.

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 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.
- **Clobazam tablets is a federally controlled substance (C-IV) because it contains clobazam that 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.

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.
 - Taking Clobazam tablets late in pregnancy may cause your baby to have symptoms of sedation (breathing problems, sluggishness, low muscle tone), and/or withdrawal symptoms (jitteriness, irritability, restlessness, shaking, excessive crying, feeding problems).
 - Tell your healthcare provider right away if you become pregnant or think you are pregnant while taking clobazam tablets.
 - 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.

- are breastfeeding or plan to breastfeed. clobazam can pass into breast milk.
 - Breastfeeding during treatment with clobazam may cause your baby to have sleepiness, feeding problems, and decreased weight gain.
 - Talk to your healthcare provider about the best way to feed your baby if you take clobazam.

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?

See “What is the most important information I should know about clobazam tablets?”

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

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 at room temperature 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.

Manufactured for:

Lupin Pharmaceuticals, Inc.
Baltimore, Maryland 21202
United States

Manufactured by:

Lupin Limited
Nagpur - 441108
India

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