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MEDICATION GUIDE

Clobazam (KLOE-ba-zam) Oral Suspension, CIV

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

- **Clobazam oral suspension 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 oral suspension 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 oral suspension affects you.
- Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking clobazam oral suspension without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, clobazam oral suspension may make your sleepiness or dizziness much worse.
- **Serious skin reactions have been seen when clobazam oral suspension is taken with other medicines and may require stopping its use.** Do not stop taking clobazam oral suspension without first talking to your healthcare provider.
 - A serious skin reaction can happen at any time during your treatment with clobazam oral suspension, 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 medicines, clobazam oral suspension 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 | ● attempts to commit suicide | ● new or worse depression |
| ● new or worse anxiety or irritability | ● feeling agitated or restless | ● an extreme increase in activity and talking (mania) |
| ● trouble sleeping (insomnia) | ● new or worse panic attacks | ● acting aggressive, being angry, or violent |
| ● acting on dangerous impulses | ● 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.

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 clobazam oral suspension?

- Clobazam oral suspension is 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 oral suspension is a federally controlled substance (C-IV) because it**

contains clobazam that can be abused or lead to dependence. Keep clobazam in a safe place to prevent misuse and abuse. Selling or giving away clobazam 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 oral suspension is safe and effective in children less than 2 years old.

Do not take clobazam oral suspension if you:

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

Before you take clobazam oral suspension, 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 oral suspension 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 oral suspension may harm your unborn baby.**
 - Tell your healthcare provider right away if you become pregnant while taking clobazam oral suspension. You and your healthcare provider will decide if you should take clobazam oral suspension while you are pregnant.
 - Babies born to mothers receiving benzodiazepine medications (including clobazam oral suspension) 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 oral suspension, 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 oral suspension. You and your healthcare provider should decide if you will take clobazam oral suspension 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 oral suspension with certain other medicines can cause side effects or affect how well clobazam oral suspension or the other medicines work. Do not start or stop other medicines without talking to your healthcare provider.

How should I take clobazam oral suspension?

- Take clobazam oral suspension exactly as your healthcare provider tells you to take it.

- Your healthcare provider will tell you how much clobazam oral suspension to take and when to take it.
- Clobazam oral suspension can be taken with or without food.
- **Shake the bottle of clobazam oral suspension right before you take each dose.**
- Measure your dose of clobazam oral suspension using the bottle adapter and dosing syringes that come with your clobazam oral suspension.
- Read the **Instructions for Use** at the end of this Medication Guide for information on the right way to use clobazam oral suspension.
- Your healthcare provider may change your dose if needed. Do not change your dose of clobazam oral suspension without talking to your healthcare provider.
- Do not stop taking clobazam oral suspension without first talking to your healthcare provider.
- Stopping clobazam oral suspension suddenly can cause serious problems.
- If you take too much clobazam oral suspension, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking clobazam oral suspension?

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

What are the possible side effects of clobazam oral suspension?

Clobazam oral suspension may cause serious side effects, including: See “What is the most important information I should know about Clobazam Oral Suspension?”

The most common side effects of clobazam oral suspension 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 oral suspension. 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 oral suspension?

- Store clobazam oral suspension at room temperature between 68°F to 77°F (20°C to 25°C).

Oral Suspension

- Replace the cap securely after opening.
- Store and dispense the oral suspension in its original bottle in an upright position. Use clobazam oral suspension within 90 days of first opening the bottle.
- After 90 days safely throw away any clobazam oral suspension that has not been used.
- **Keep clobazam oral suspension and all medicines out of the reach of children.**

General information about the safe and effective use of clobazam oral suspension.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use clobazam oral suspension for a condition for which it was not prescribed. Do not give clobazam oral suspension 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 oral suspension that is written for health professionals.

What are the ingredients in clobazam oral suspension?

Active ingredient: clobazam

Inactive ingredients: citric acid monohydrate, disodium hydrogen phosphate dihydrate, magnesium aluminium silicate, maltitol solution, methyl paraben, polysorbate, propylene glycol, propyl paraben, raspberry flavour, saccharine sodium, simethicone emulsion, sucralose, and xanthan gum

Manufactured for:

Lupin Pharmaceuticals, Inc.

Baltimore, Maryland 21202

United States

Manufactured by:

Lupin Limited

Aurangabad - 431210

India

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

Instructions for Use

Clobazam (KLOE-ba-zam) Oral Suspension, CIV

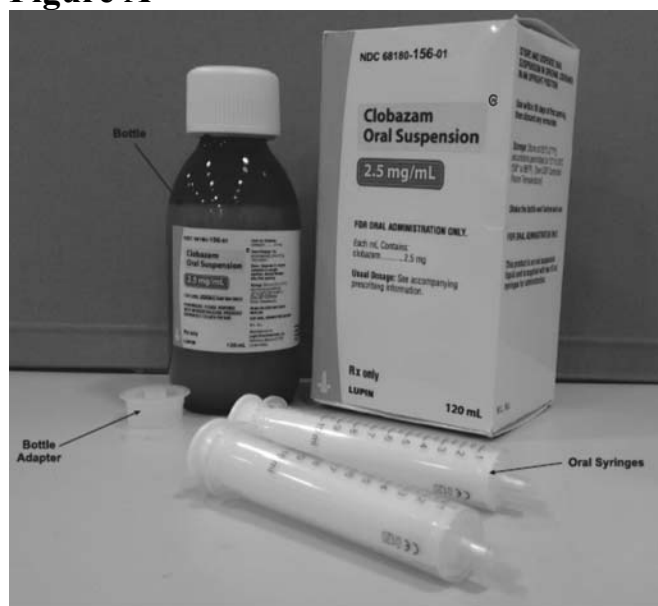
Read this Instructions for Use before using clobazam oral suspension and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or treatment.

Prepare Clobazam Oral Suspension Dose

You will need the following supplies: **See Figure A**

- Clobazam oral suspension bottle
- Bottle adapter
- Oral dosing oral syringe (2 dosing oral syringes are included in the clobazam oral suspension box).
- Use only 1 oral syringe to take your dose of clobazam oral suspension. If you lose or damage the oral syringe, or cannot read the markings, use the other oral syringe.

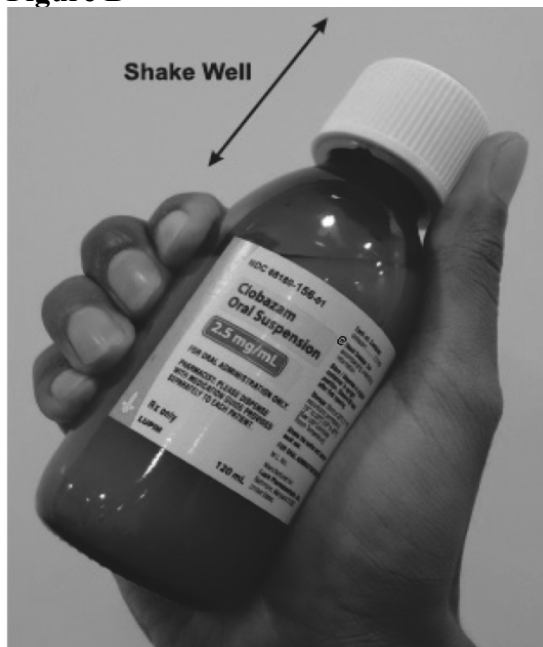
Figure A



Step 1. Remove the clobazam oral suspension bottle, bottle adapter, and 1 oral syringe from the box.

Step 2. Shake the bottle well before each use. **See Figure B**

Figure B



Step 3. Uncap the bottle and firmly insert the bottle adapter into the bottle until the adapter top is even with the bottle top. **See Figure C**

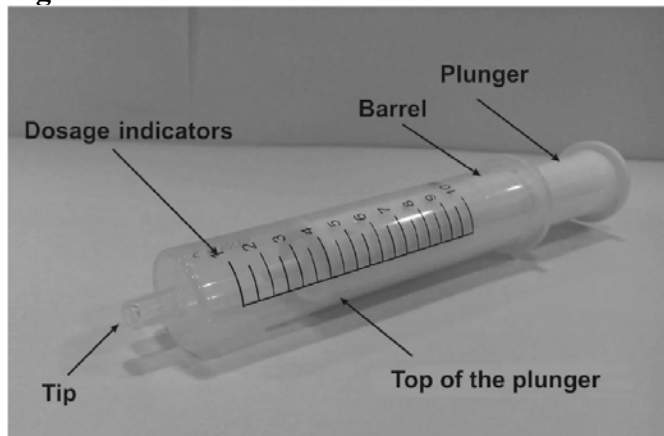
Figure C



Once the bottle adapter is in place, it should not be removed.

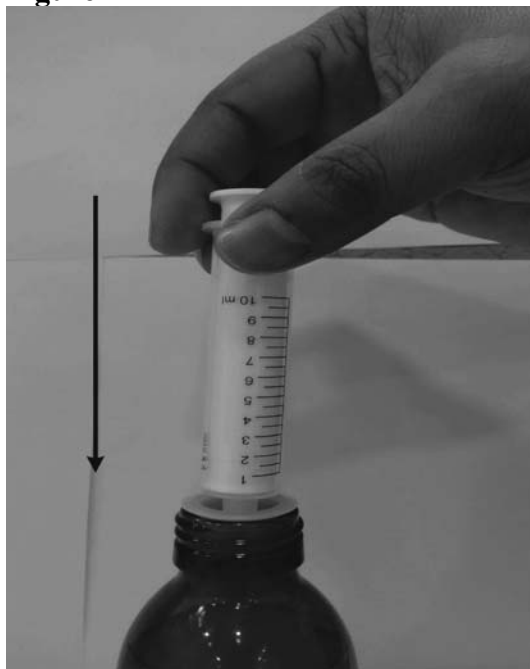
Step 4. Check your dose in milliliters (mL) as prescribed by your healthcare provider. Find this number on the oral syringe. Do not take more than the prescribed total dose in 1 day. **See Figure D**

Figure D



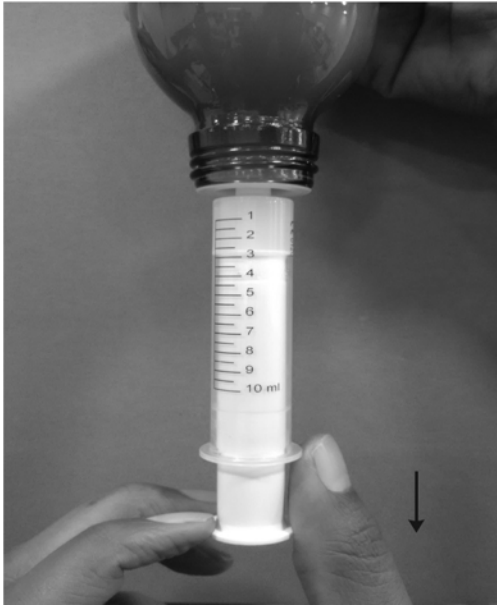
Step 5. Push the plunger all the way down and then insert the oral syringe into the upright bottle through the opening in the bottle adapter. **See Figure E**

Figure E



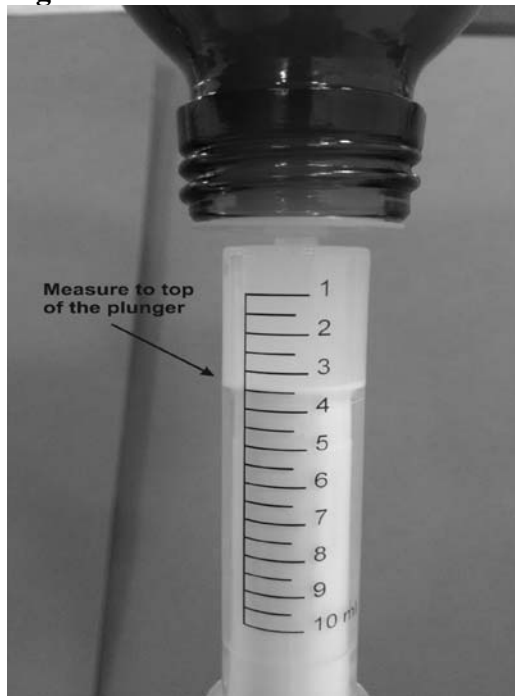
Step 6. With the oral syringe in place, turn the bottle upside down. Pull the plunger to the number of mLs needed (the amount of liquid medicine in Step 4). **See Figure F**

Figure F



Measure the mLs of medicine using the top of the plunger on the white plunger. See **Figure G**

Figure G



Step 7. Remove the oral syringe from the bottle adapter. Slowly squirt clobazam oral suspension directly into the corner of your mouth or your child's mouth until all of the liquid medicine in the oral syringe is given. See **Figure H**

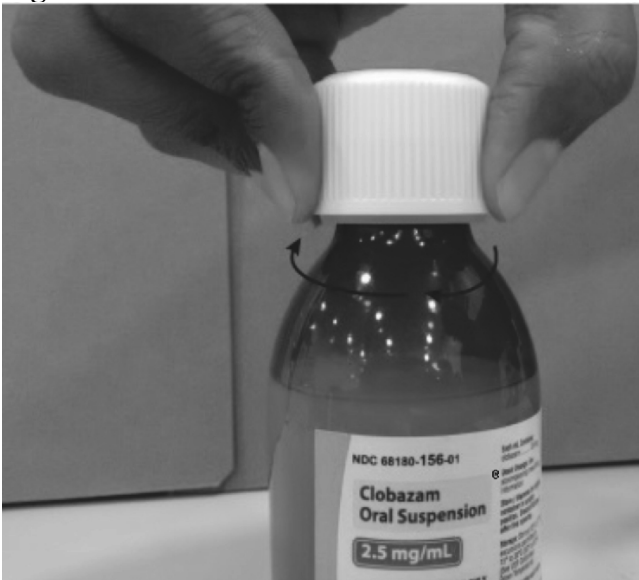
Figure H



Step 8. Cap the bottle tightly with the adapter in place. If the cap does not fit securely, check to see if the adapter is fully inserted. **See Figure I**

- Store and dispense clobazam oral suspension in its original bottle in an upright position at 68°F to 77°F (20°C to 25°C).
- Use clobazam oral suspension within 90 days of first opening bottle.
- After 90 days safely throw away any clobazam oral suspension that has not been used.

Figure I



Step 9. Wash the oral syringe after each use.

- To clean the oral syringe, take apart by removing the plunger completely.

- Pull plunger straight out of the barrel.
- The barrel and plunger can be washed with soap and water, rinsed, and allowed to dry.
 - Do not wash the oral syringe in the dishwasher.

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