What is the most important information I should know about clobazam oral suspension?

- Do not stop taking clobazam oral suspension without first talking to your healthcare provider. Stopping clobazam oral suspension suddenly can cause serious side effects.
- Clobazam oral suspension is a benzodiazepine medicine. Benzodiazepines can cause drowsiness, breathing problems (respiratory depression), coma, and death when taken with opioid medicines.
- Clobazam oral suspension 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 oral suspension affects you.
  - Clobazam oral suspension 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 oral suspension unless you talk 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.
- Clobazam oral suspension can cause withdrawal symptoms.
  - Do not stop taking clobazam oral suspension all of a sudden without first talking to a healthcare provider. Stopping clobazam oral suspension suddenly can cause seizures that will 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 oral suspension to avoid withdrawal symptoms.
- Clobazam oral suspension 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 controlled substance (CIV) because it can be abused or lead to dependence. Any clobazam oral suspension is in a safe place to prevent misuse and abuse. Selling or giving away clobazam oral suspension may harm others and to get on the black market. 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 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. It is more likely to happen in the first 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, rashes, or any other allergic reaction.
- Like other antiepileptic drugs, clobazam oral suspension may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.
  - Talk to your healthcare provider about how to monitor for suicidal thoughts and actions.
- How can I watch for early signs 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 have 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. 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.
- are taking any prescription or OTC medicines with clobazam oral suspension or certain other medicines, to be sure the medicines do not interact and cause serious side effects. Take your medicines with clobazam oral suspension exactly as you were told by your healthcare provider.

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 other medicines, to be sure the medicines do not interact and cause serious side effects.

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 syringe 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?

- 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 medicines that may make you sleepless or dizzy while taking clobazam oral suspension until you talk to your healthcare provider.
- When taken with alcohol or medicines that cause sleepiness or dizziness, clobazam oral suspension may make your sleepiness or dizziness much worse.

What are the possible side effects of clobazam oral suspension?

Clobazam oral suspension may cause serious side effects, including:

What is the most important information I should know about clobazam oral suspension?

The most common side effects of clobazam oral suspension include:

- sleepiness
- drowsiness
- constipation
- cough
- pain with urination
- fever
- acting aggressive, being angry, or violent
- difficulty sleeping
- slurred speech
- tremors
- 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.

How should I store clobazam oral suspension?

- Store clobazam oral suspension between 68°F to 77°F (20°C to 25°C).
- Replace the cap securely after opening.
- Store and dispense the clobazam 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 cllobazam oral suspension?

Active Ingredient: cllobazam

Inactive ingredients: citric acid monohydrate, dibasic sodium phosphate anhydrous, magnesium aluminum silicate, methyl paraben, polysorbate 80, propylene glycol, proxyl paraben, purified water, simethicone emulsion, strawberry flavor, sucralose and sulfuric gum.

Manufactured by:
Northstar Rx LLC
Memphis, TN 38141.

For more information about cllobazam oral suspension, Northstar Rx LLC at 1-800-206-7261.

This Medication Guide has been approved by the U.S. Food and Drug Administration Medication Guides available at www.northstarrx.com/products or call 1-888-206-7261

Instructions for Use
Cllobazam (Kloep®) Oral Suspension, CIV

Read this Instructions for Use before using cllobazam 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 Cllobazam Oral Suspension Dose

You will need the following supplies: See Figure A

- Cllobazam oral suspension bottle
- Bottle adapter
- Oral dosing syringe (2 dosing oral syringes are included in the cllobazam oral suspension box)

Use only 1 oral syringe to take your dose of cllobazam 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 cllobazam 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. Unscrew 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

Step 7. Remove the oral syringe from the bottle adapter. Slowly squat cllobazam 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

Figure I

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

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured by:
Northstar Rx LLC
Memphis, TN 38141.

Manufactured by:
Hetero Labs Limited
Jeddah, Hyderabid - 500 055, India

Revised: 03/2020