

Medication Guide
Lorazepam Oral Concentrate, USP, CIV
(lor A ze pam)

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

- **Lorazepam is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system 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 lorazepam with opioids affects you.
- **Risk of abuse, misuse, and addiction.** There is a risk of abuse, misuse, and addiction with benzodiazepines including lorazepam 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 lorazepam.** 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 lorazepam exactly as prescribed by your healthcare provider.**
 - **Take lorazepam exactly as your healthcare provider prescribed.**
 - Do not share your lorazepam with other people.
 - Keep lorazepam in a safe place and away from children.
- **Physical dependence and withdrawal reactions.** Lorazepam can cause physical dependence and withdrawal reactions.
 - **Do not suddenly stop taking lorazepam.** Stopping lorazepam 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 lorazepam than prescribed or take lorazepam for longer than prescribed.

What is lorazepam?

Lorazepam is a prescription medicine used:

- to treat anxiety disorders
 - for the short-term relief of the symptoms of anxiety or anxiety that can happen with symptoms of depression
 - **Lorazepam is a federal controlled substance (C-IV) because it can be abused or lead to dependence.** Keep lorazepam in a safe place to prevent misuse and abuse. Selling or giving away

lorazepam may harm others, and is against the law. Tell your healthcare provider if you have abused or been dependent on alcohol, prescription medicines or street drugs.

- It is not known if lorazepam is safe and effective for use in children less than 12 years of age.
- It is not known if lorazepam is safe and effective for use for longer than 4 months.

Do not take lorazepam if you:

- are allergic to lorazepam, other benzodiazepines, or any of the ingredients in Lorazepam Oral Concentrate. See the end of this Medication Guide for a complete list of ingredients in Lorazepam Oral Concentrate.

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

- have or have had depression, mood problems, or suicidal thoughts or behavior
- have a history of drug or alcohol abuse or addiction
- have lung disease or breathing problems (such as COPD, sleep apnea syndrome)
- have liver or kidney problems
- have or have had seizures
- are pregnant or plan to become pregnant.
- Taking lorazepam 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 during treatment with lorazepam.
- There is a pregnancy registry for women who take lorazepam during pregnancy. The purpose of the registry is to collect information about the health of you and your baby. If you become pregnant during treatment with lorazepam, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychiatric Medications. You can register by calling 1-866-961-2388 or visiting <https://womensmentalhealth.org/pregnancyregistry/>.
- are breastfeeding or plan to breastfeed. Lorazepam passes into your breast milk.
- Breastfeeding during treatment of lorazepam 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 lorazepam.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Taking lorazepam with certain other medicines can cause side effects or affect how well lorazepam or the other medicines work. Do not start or stop other medicines without talking to your healthcare provider.

How should I take lorazepam?

- Take lorazepam exactly as your healthcare provider tells you to take it. Your healthcare provider will tell you how much lorazepam to take and when to take it.
- If you take too much lorazepam, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of lorazepam?

Lorazepam may cause serious side effects, including:

- See “What is the most important information I should know about lorazepam?”
 - Lorazepam 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 lorazepam affects you.

- **Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking lorazepam without first talking to your healthcare provider.** When taken with alcohol or drugs that cause sleepiness or dizziness, lorazepam may make your sleepiness or dizziness much worse.
- **Depression.** Pre-existing depression may emerge or worsen during use of benzodiazepines including lorazepam.

The most common side effects of lorazepam include:

- sedation
- weakness
- dizziness
- unsteadiness

These are not all the possible side effects of lorazepam. 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 lorazepam?

- Store lorazepam at a cold temperature. Refrigerate at 2°C to 8°C (36°F to 46°F) and protect from light.
- **Keep lorazepam and all medicines out of the reach of children.**

General information about the safe and effective use of lorazepam.

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

What are the ingredients in Lorazepam Oral Concentrate?

Active ingredient: lorazepam

Inactive ingredients: polyethylene glycol and propylene glycol.

For information, please call 1-845-232-1683.

Manufactured for:
Chartwell RX, LLC.
Congers, NY 10920

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