

**MEDICATION GUIDE**  
**LOREEV XR (lor-EEV ECKS-AR)**  
**(lorazepam)**  
**extended-release capsules, CIV**

**What is the most important information I should know about LOREEV XR?**

**LOREEV XR may cause serious side effects, including:**

- **LOREEV XR 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 LOREEV XR with opioids affects you.
- **Risk of abuse, misuse, and addiction.** There is a risk for abuse, misuse, and addiction with benzodiazepines including LOREEV XR 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 LOREEV XR.** 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 develop any of these serious side effects.**
  - **You can develop an addiction even if you take LOREEV XR as prescribed by your healthcare provider.**
  - **Take LOREEV XR exactly as your healthcare provider prescribed.**
  - Do not share your LOREEV XR with other people.
  - Keep LOREEV XR in a safe place and away from children.
- **Physical dependence and withdrawal reactions.** LOREEV XR can cause physical dependence and withdrawal reactions, especially if you continue to take LOREEV XR for several days to several weeks.
  - **Do not suddenly stop taking LOREEV XR.** Stopping LOREEV XR 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 develop any of these serious side effects.**
  - **Some people who stop taking 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 LOREEV XR than prescribed or take LOREEV XR for longer than prescribed.

**What is LOREEV XR?**

LOREEV XR is a prescription medicine used to treat anxiety disorders in adults who are receiving stable, evenly divided, 3 times a day dosing with lorazepam tablets.

- **LOREEV XR is a federally controlled substance (CIV) because it contains lorazepam that can be abused or lead to dependence.** Keep LOREEV XR in a safe place to prevent misuse and abuse. Selling or giving away LOREEV XR 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 LOREEV XR is safe or effective in children.
- It is not known if LOREEV XR is safe and effective for use for longer than 4 months.

**Do not take LOREEV XR if you:**

- are allergic to lorazepam, other benzodiazepines, or any of the ingredients in LOREEV XR. See the end of this Medication Guide for a complete list of ingredients in LOREEV XR.
- have acute narrow angle glaucoma

**Before taking LOREEV XR, tell your healthcare provider about all of 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. LOREEV XR may harm your unborn baby.
  - If you become pregnant while taking LOREEV XR, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychiatric Medications during pregnancy. You can register by calling 1-866-961-2388 or visit <https://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/othermedications>
  - Babies born to mothers who take benzodiazepines, including LOREEV XR late in pregnancy may have symptoms of sedation such as breathing problems, sluggishness, low muscle tone (floppy baby syndrome), feeding problems, and withdrawal symptoms.
- are breastfeeding or plan to breastfeed. LOREEV XR passes into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby during treatment with LOREEV XR. You should not breastfeed during treatment with LOREEV XR.

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

Keep a list of all medicines to show your healthcare provider and pharmacist when you get a new medicine.

LOREEV XR can affect the way other medicines work and other medicines may affect how LOREEV XR works. Taking LOREEV XR with certain other medicines can cause serious side effects.

**Do not start or stop other medicines without first talking to your healthcare provider.**

**How should I take LOREEV XR?**

- Take LOREEV XR exactly as your healthcare provider tells you to take it.
- Take LOREEV XR 1 time a day in the morning.
- Take LOREEV XR with or without food.
- Do not crush or chew LOREEV XR capsules.
- Swallow LOREEV XR capsules whole. If you cannot swallow the capsules whole, the capsule may be opened and the entire contents sprinkled onto a tablespoon of applesauce.
  - Swallow all the LOREEV XR mixture without chewing.
  - Swallow the LOREEV XR mixture within 2 hours of mixing. Do not store the mixture for future use.
  - After swallowing the LOREEV XR mixture, follow with a drink of water.
- If you take too much LOREEV XR, call your healthcare provider or poison control center at 1-800-222-1222 or go to the nearest hospital emergency room right away.

**What should I avoid while taking LOREEV XR?**

- LOREEV XR can cause you to be drowsy. Do not drive a car or operate heavy machinery until you know how LOREEV XR affects you.
- You should not drink alcohol during treatment with LOREEV XR. Drinking alcohol can increase your chances of

having serious side effects.

### What are the possible side effects of LOREEV XR?

LOREEV XR may cause serious side effects, including:

- See “What is the most important information I should know about LOREEV XR?”
- **LOREEV XR 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 LOREEV XR affects you.
  - Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking LOREEV XR without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, LOREEV XR may make your sleepiness or dizziness much worse.
- **Depression and psychosis.** Pre-existing depression may emerge or worsen during use of benzodiazepines including LOREEV XR.
- **Abnormal thought and behavior (paradoxical reactions).** Symptoms include agitation, irritability, impulsiveness, violent behavior, confusion, restlessness, excitement and talking more than normal.
- **Allergic reactions to FD&C Yellow No. 5.** LOREEV XR 1 mg capsules contain FD&C Yellow No. 5 (tartrazine), which may cause allergic type reactions in certain people. Symptoms may include bronchial asthma or trouble breathing. Get emergency medical help right away if you have these symptoms after taking LOREEV XR.
- **Breathing problems.** Slowed breathing and stopping breathing has happened in people who have breathing problems and take benzodiazepines like LOREEV XR.
- **Changes in lab tests.** Your healthcare provider should do blood tests to check your blood counts and your liver function during treatment if you are on long-term treatment with LOREEV XR.

The most common side effects of LOREEV XR include sedation, dizziness, weakness, unsteadiness.

These are not all the possible side effects of LOREEV XR.

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 LOREEV XR?

- Store LOREEV XR in a tightly closed container at room temperature between 68°F to 77°F (20°C to 25°C).
- **Keep LOREEV XR and all medicines out of the reach of children.**

### General information about the safe and effective use of LOREEV XR.

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

### What are the ingredients in LOREEV XR?

**Active ingredient:** lorazepam

**Inactive ingredients:** colloidal silicon dioxide, corn starch, gelatin, glyceryl monostearate, hypromellose, lactose monohydrate, methyl acrylate methyl methacrylate and methacrylic acid (7:3:1) copolymer 280000 dispersion, microcrystalline cellulose, polysorbate 80, talc, titanium dioxide, and triethyl citrate. Additionally, the capsule shells contain the following colorants:

1 mg capsules: FD&C Yellow No. 5

1.5 mg capsules: FD&C Blue No. 1 and FD&C Red No. 3

2 mg capsules: D&C Yellow No. 10 and FD&C Red No. 3

3 mg capsules: D&C Yellow No. 10, FD&C Blue No. 1, FD&C Yellow No. 6

Distributed by: Almatica Pharma LLC, Morristown, NJ 07960 USA

Loreev XR is protected by U.S. Patent No. 8,999,393.

Loreev XR is a registered trademark of Almatica Pharma LLC.

For more information, visit [www.loreevxr.com](http://www.loreevxr.com) or call 1-877-447-7979.

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

Revised: 12/2021

PL658-01