

## MEDICATION GUIDE

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### MEDICATION GUIDE

#### Oxazepam (ox az' e pam) Capsules, C-IV

##### What is the most important information I should know about oxazepam?

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

#### **What is oxazepam?**

- Oxazepam 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 depression
  - to treat anxiety, tension, agitation and irritability in elderly people
  - to relieve the symptoms of alcohol withdrawal including agitation, shakiness (tremor), anxiety associated with acute alcohol withdrawal.
- **Oxazepam is a federal controlled substance (C-IV) because it contains oxazepam that can be abused or lead to dependence.** Keep oxazepam in a safe place to prevent misuse and abuse. Selling or giving away oxazepam 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 oxazepam is safe and effective in children under 6 years of age.
- It is known if oxazepam is safe and effective for use longer than 4 months.

#### **Do not take oxazepam if you:**

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

#### **Before you take oxazepam, 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 liver or kidney problems
- have or have had problems with fainting or low blood pressure
- are pregnant or plan to become pregnant..
  - Taking oxazepam late in pregnancy may cause your baby to have symptoms of sedation (breathing problems, sluggishness, low muscle tone), and/or withdrawal symptom (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 oxazepam.
- are breastfeeding or plan to breastfeed. Oxazepam may pass into your breast milk.
  - Breastfeeding during treatment with oxazepam 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 oxazepam.

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

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

#### **How should I take oxazepam?**

- See “**What is the most important information I should know about oxazepam?**”
- Take oxazepam exactly as your healthcare provider tells you to take it. Your healthcare provider will tell you how much oxazepam to take and when to take it.
- If you take too much oxazepam, call your healthcare provider or go to the nearest hospital emergency room right away.

#### **What are the possible side effects of oxazepam?**

##### **Oxazepam may cause serious side effects, including:**

- See “**What is the most important information I should know about oxazepam?**”
- **Low blood pressure.** Oxazepam can cause low blood pressure especially in elderly people.
- **Oxazepam 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 oxazepam affects you.
  - Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking oxazepam without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, oxazepam may make your sleepiness or dizziness much worse.

##### **The most common side effects of oxazepam include:**

- drowsiness
- dizziness
- vertigo
- headache

These are not all the possible side effects of oxazepam. 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 oxazepam?**

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

#### **General information about the safe and effective use of oxazepam capsules.**

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

#### **What are the ingredients in oxazepam?**

**Active ingredient:** Oxazepam

**Inactive ingredients:** hypromellose, lactose (monohydrate), magnesium stearate and corn starch. The capsule shells and imprinting inks contain: gelatin, titanium dioxide, shellac, black iron oxide, propylene glycol and D&C Red #7 Calcium Lake E180. The 10 mg capsules also contain: methylparaben, butylparaben, propylparaben, benzyl alcohol, sodium propionate, edetate calcium disodium and sodium lauryl sulfate. The 15 mg ink also contains: D&C Yellow #10 Aluminum Lake. The 30 mg ink also contains: FD&C Red #40 Aluminum Lake #129 and FD&C Blue #2 Aluminum Lake #132.

For more information, call 1-888-374-2791.

Manufactured For:  
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Princeton, NJ 08540

This Medication Guide has been approved by the U.S. Food and Drug Administration. Rev. 08-2022-00