

MEDICATION GUIDE
Alprazolam (al pra' zoe lam)
Tablets, USP, C-IV

What is the most important information I should know about alprazolam tablets?

- **Alprazolam tablets are 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 alprazolam tablets with opioids affects you.

- **Risk of abuse, misuse, and addiction.** There is a risk of abuse, misuse, and addiction with benzodiazepines, including alprazolam tablets, 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 alprazolam tablets.** 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 alprazolam tablets as prescribed by your healthcare provider.**
 - **Take alprazolam tablets exactly as your healthcare provider prescribed.**
 - Do not share your alprazolam tablets with other people.
 - Keep alprazolam tablets in a safe place and away from children.
- **Physical dependence and withdrawal reactions.** Alprazolam tablets can cause physical dependence and withdrawal reactions.
 - **Do not suddenly stop taking alprazolam tablets.** Stopping alprazolam tablets 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 alprazolam tablets than prescribed or take alprazolam tablets for longer than prescribed.

What are alprazolam Tablets?

- Alprazolam Tablets are a prescription medicine used:
 - to treat anxiety disorders
 - for the short-term relief of the symptoms of anxiety
 - to treat panic disorder with or without a fear of places and situations that might cause panic, helplessness, or embarrassment (agoraphobia)
- **Alprazolam tablets are a federal controlled substance (C-IV) because they contain alprazolam that can be abused or lead to dependence.** Keep alprazolam tablets in a safe

place to prevent misuse and abuse. Selling or giving away alprazolam tablets 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 alprazolam tablets are safe and effective in children.
- Elderly patients are especially susceptible to dose related adverse effects when taking alprazolam tablets.
- It is not known if alprazolam tablets are safe and effective when used to treat anxiety disorder for longer than 4 months.
- It is not known if alprazolam tablets are safe and effective when used to treat panic disorder for longer than 10 weeks.

Do not take alprazolam tablets if:

- you are allergic to alprazolam, other benzodiazepines, or any of the ingredients in alprazolam tablets. See the end of this Medication Guide for a complete list of ingredients in alprazolam tablets.
- you are taking antifungal medicines including ketoconazole and itraconazole.

Before you take alprazolam tablets, 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 lung disease or breathing problems
- are pregnant or plan to become pregnant. Alprazolam tablets may harm your unborn baby. You and your healthcare provider should decide if you should take alprazolam tablets while you are pregnant.
- are breastfeeding or plan to breastfeed. Alprazolam passes into your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take alprazolam tablets. You should not breastfeed while taking alprazolam tablets.

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

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

How should I take alprazolam tablets?

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

What are the possible side effects of alprazolam tablets?

Alprazolam Tablets may cause serious side effects, including:

- See "What is the most important information I should know about alprazolam tablets?"
- **Seizures.** Stopping alprazolam tablets can cause seizures and seizures that will not stop (status epilepticus).
- **Mania.** Alprazolam tablets may cause an increase in activity and talking (hypomania and mania) in people who have depression.
 - **Alprazolam tablets 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 alprazolam tablets affect you.
 - **Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking alprazolam tablets without first talking to your healthcare provider.** When taken with alcohol or drugs that cause sleepiness or dizziness, alprazolam tablets may make your sleepiness or dizziness much worse.

The most common side effects of alprazolam tablets include:

- problems with coordination
- hypotension
- trouble saying words clearly (dysarthria)
- changes in sex drive (libido)

These are not all the possible side effects of alprazolam tablets. 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 alprazolam tablets?

- Store alprazolam tablets at room temperature between 68°F to 77°F (20°C to 25°C)
- **Keep alprazolam tablets and all medicines out of the reach of children.**

General information about the safe and effective use of alprazolam tablets.

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

What are the ingredients in alprazolam tablets?

Active ingredient: alprazolam

Inactive ingredients: Lactose monohydrate, microcrystalline cellulose, sodium starch glycolate, hydroxyl propyl cellulose, sodium lauryl sulfate and magnesium stearate. In addition, the 0.5 mg tablet contains FD&C Yellow 6 lake and the 1 mg and 2 mg tablets contain FD&C Blue 2 lake.

For more information, go to www.bpirx.com or call Breckenridge Pharmaceutical, Inc. 1-800-367-3395.

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

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