

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 depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma and death.**
- **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.
- Do not take more alprazolam tablets 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 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 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 many alprazolam tablets to take and when to take them.
- If you take too many alprazolam tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking alprazolam tablets?

- Alprazolam tablets can cause you to be drowsy. Do not drive a car or operate heavy machinery until you know how alprazolam tablets affect you.
- You should not drink alcohol while taking alprazolam tablets. Drinking alcohol can increase your chances of having serious side effects.

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?”**
- **Abuse and dependence.** Taking alprazolam tablets can cause physical and psychological dependence. Physical and psychological dependence is not the same as drug addiction. Your healthcare provider can tell you more about the differences between physical and psychological dependence and drug addiction.
- **Withdrawal symptoms.** You may have withdrawal symptoms if you stop taking alprazolam tablets suddenly. Withdrawal symptoms can be serious and include seizures. Mild withdrawal symptoms include a depressed mood and trouble sleeping. Talk to your healthcare provider about slowly stopping alprazolam tablets to avoid withdrawal symptoms.
- **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.

The most common side effects of alprazolam tablets include drowsiness and light-headedness. 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 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 they were 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. For more information call Actavis at 1-888-838-2872.

What are the ingredients in alprazolam tablets?

Active ingredient: alprazolam, USP

Inactive ingredients: colloidal silicon dioxide, corn starch, docusate sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, and sodium benzoate. The 0.5 mg tablet also contains FD&C yellow #6 aluminum lake (sunset yellow lake). The 1 mg tablet also contains FD&C blue #2 aluminum lake. The 2 mg tablet also contains D&C yellow #10 aluminum lake.

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

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