

MEDICATION GUIDE
ALPRAZOLAM Tablets, C-IV

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

- **Alprazolam 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.**
- **Alprazolam 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 affects you.
 - Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking alprazolam without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, alprazolam may make your sleepiness or dizziness much worse.
- Do not take more alprazolam than prescribed.

What is alprazolam?

- Alprazolam is 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 is a federal controlled substance (C-IV) because it can be abused or lead to dependence.** Keep alprazolam in a safe place to prevent misuse and abuse. Selling or giving away alprazolam 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 is safe and effective in children.
- Elderly patients are especially susceptible to dose related adverse effects when taking alprazolam.
- It is not known if alprazolam is safe and effective when used to treat anxiety disorder for longer than 4 months.
- It is not known if alprazolam is safe and effective when used to treat panic disorder for longer than 10 weeks.

Do not take alprazolam if:

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

Before you take alprazolam, 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 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. You should not breastfeed while taking alprazolam.

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

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

How should I take alprazolam?

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

What should I avoid while taking alprazolam?

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

What are the possible side effects of alprazolam?

Alprazolam may cause serious side effects, including:

- See "**What is the most important information I should know about alprazolam?**"
- **Abuse and dependence.** Taking alprazolam 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 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 to avoid withdrawal symptoms.
- **Seizures.** Stopping alprazolam can cause seizures and seizures that will not stop (status epilepticus).
- **Mania.** Alprazolam may cause an increase in activity and talking (hypomania and mania) in people who have depression.

The most common side effects of alprazolam include drowsiness and light-headedness. These are not all the possible side effects of alprazolam. 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?

- Store alprazolam between 68°F to 77°F 20°C to 25°C
- **Keep alprazolam and all medicines out of the reach of children.**

General information about the safe and effective use of alprazolam.

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

What are the ingredients in alprazolam?

Active ingredient: alprazolam

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Inactive ingredients: Cellulose, corn starch, docusate sodium, lactose, magnesium stearate, silicon dioxide and sodium benzoate. In addition, the 0.5 mg tablet contains FD&C Yellow No. 6 and the 1 mg tablet contains FD&C Blue No. 2.

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

This product's label may have been updated. For current full prescribing information, please visit www.greenstonellc.com.



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