MEDICATION GUIDE

Alprazolam (al-PRAE-zoe-lam) Orally Disintegrating Tablet (ODT), C-IV

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

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

What is Alprazolam ODT?

- Alprazolam ODT is a prescription medicines used to treat:
- generalized anxiety disorder
- panic disorder with or without fear of places and situations that might cause panic, helplessness, or embarrassment (agoraphobia)
- **Alprazolam ODT is a federal controlled substance (C-IV) because it can be abused or lead to dependence**. Keep alprazolam ODT in a safe place to prevent misuse and abuse. Selling or giving away alprazolam ODT 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 ODT is safe and effective in children.
- It is not known if alprazolam ODT is safe and effective when to treat generalized anxiety disorder for longer than 4 months.
- It is not known if alprazolam ODT is safe and effective when used to treat panic disorder for longer than 10 weeks.

Do not take alprazolam ODT if you:

- take an antifungal medicines including ketoconazole and itraconazole

Before you take alprazolam ODT, tell your healthcare provider about all 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 ODT may harm your unborn baby. You and your healthcare provider should decide if you should take alprazolam ODT while you are pregnant.

- are breastfeeding or plan to breastfeed. Alprazolam ODT 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 ODT. You should not breastfeed while taking alprazolam ODT.

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

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

How should I take alprazolam ODT?

- Take alprazolam ODT exactly as your healthcare provider tells you to take it. Your healthcare provider will tell you how much alprazolam ODT to take and when to take it.
- Do not remove alprazolam ODT from the blister until you are ready to take it. With dry hands, remove the alprazolam ODT, and immediately place on your tongue to dissolve and be swallowed with your saliva. The tablet may also be taken with water.

- If you take too much alprazolam ODT, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking alprazolam ODT?

- Alprazolam ODT can cause you to be drowsy. Do not drive a car or operate heavy machinery until you know how alprazolam ODT affects you.

- You should not drink alcohol while taking alprazolam ODT. Drinking alcohol can increase your chances of having serious side effects.

What are the possible side effects of alprazolam ODT?

alprazolam ODT may cause serious side effects, including:

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

- **Abuse and dependence.** Taking alprazolam ODT 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 ODT 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 ODT to avoid withdrawal symptoms.

- **Seizures.** Stopping alprazolam ODT can cause seizures and seizures that will not stop (status epilepticus).
- **Mania.** Alprazolam ODT may cause an increase in activity and talking (hypomania and mania) in people who have depression.

The most common side effects of alprazolam ODT include:

- sedation
- problems with coordination
- speech problems (dysarthria)
- increased libido
- low blood pressure (hypotension)

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

- Store alprazolam ODT at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep alprazolam ODT in a tightly closed container and keep dry.

Keep alprazolam ODT and all medicines out of the reach of children.

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

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

What are the ingredients in alprazolam ODT?

Active ingredients: alprazolam

Inactive ingredients: aspartame, crospovidone, basic butylated methacrylate copolymer, magnesium stearate, mannitol, silicon dioxide, sorbitol, talc, xylitol, natural peppermint flavor, artificial vanillin flavor.

Manufactured by:

PAR PHARMACEUTICAL

Chestnut Ridge, NY 10977

For more information call 1-800-828-9393.

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

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