MEDICATION GUIDE

CLONAZEPAM ODT (kloe naz e pam) Orally Disintegrating Tablet (ODT), C-IV



Phenylketonurics: Each clonazepam orally disintegrating tablet contains 0.56 mg phenylalanine (a component of aspartame).

Read this Medication Guide before you start taking Clonazepam Orally Disintegrating Tablets and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment.

Clonazepam can cause serious side effects. Because stopping clonazepam suddenly can also cause serious problems, do not stop taking clonazepam without talking to your healthcare provider first.

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

- **Do not stop taking CLONAZEPAM ODT without first talking to your healthcare provider.** Stopping CLONAZEPAM ODT suddenly can cause serious side effects.
- **CLONAZEPAM ODT is a benzodiazepine medicine. Benzodiazepines can cause severe drowsiness, breathing problems (respiratory depression), coma, and death when taken with opioid medicines.**
- **CLONAZEPAM ODT can make you sleepy or dizzy and can slow your thinking and motor skills. This may get better over time.**
- Do not drive, operate heavy machinery, or do other dangerous activities until you know how CLONAZEPAM ODT affects you.
- CLONAZEPAM ODT may cause problems with your coordination, especially when you are walking or picking things up.
- **Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking CLONAZEPAM ODT until you talk to your healthcare provider.** When taken with alcohol or drugs that cause sleepiness or dizziness, CLONAZEPAM ODT may make your sleepiness or dizziness worse.
- **Like other antiepileptic drugs, CLONAZEPAM ODT may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.**

Call a healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you:

- thoughts about suicide or dying
- attempt to commit suicide
- new or worse depression
- new or worse anxiety
- feeling agitated or restless
- panic attacks
- trouble sleeping (insomnia)
- new or worse irritability
- acting aggressive, being angry, or violent
- acting on dangerous impulses
- an extreme increase in activity and talking (mania)
- other unusual changes in behavior or mood

How can I watch for early symptoms of suicidal thoughts and actions?

- Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- Keep all follow-up visits with your healthcare provider as scheduled.

Call your healthcare provider between visits as needed, especially if you are worried about symptoms.

Suicidal thoughts or actions can be caused by things other than medicines. If you have suicidal thoughts or actions, your healthcare provider may check for other causes.

- **Do not stop CLONAZEPAM ODT without first talking to a healthcare provider.**

- Stopping CLONAZEPAM ODT suddenly can cause serious problems. Stopping CLONAZEPAM ODT suddenly can cause seizures that will not stop (status epilepticus).

- **CLONAZEPAM ODT may harm your unborn or developing baby.**

- If you take CLONAZEPAM ODT during pregnancy, your baby is at risk for serious birth defects. These defects can happen as early as in the first month of pregnancy, even before you know you are pregnant. Birth defects may occur even in children born to women who are not taking any medicines and do not have other risk factors.
- Children born to mothers receiving benzodiazepine medications (including CLONAZEPAM ODT) late in pregnancy may be at some risk of experiencing breathing problems, feeding problems, hypothermia, and withdrawal symptoms.
- Tell your healthcare provider right away if you become pregnant while taking CLONAZEPAM ODT. You and your healthcare provider should decide if you will take CLONAZEPAM ODT while you are pregnant.
- If you become pregnant while taking CLONAZEPAM ODT, talk to your healthcare provider about registering with the North American Antiepileptic Drug Pregnancy Registry. You can register by calling 1-888-233-2334. The purpose of this registry is to collect information about the safety of antiepileptic drugs during pregnancy.
- CLONAZEPAM ODT can pass into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take CLONAZEPAM ODT. You and your healthcare provider should decide if you will take CLONAZEPAM ODT or breast feed. You should not do both.

- **CLONAZEPAM ODT can cause abuse and dependence.**

- Do not stop taking CLONAZEPAM ODT all of a sudden. Stopping CLONAZEPAM ODT suddenly can cause seizures that do not stop, hearing or seeing things that are not there (hallucinations), shaking, and stomach and muscle cramps.
- Talk to your healthcare provider about slowly stopping CLONAZEPAM ODT to avoid withdrawal symptoms.
- 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.

- **CLONAZEPAM ODT is a federal controlled substance (C-IV) because it can be abused or lead to dependence.** Keep CLONAZEPAM ODT in a safe place to prevent misuse and abuse. Selling or giving away CLONAZEPAM ODT may harm others, and is against the law. Tell your healthcare provider if you have ever abused or been dependent on alcohol, prescription medicines or street drugs.

What is CLONAZEPAM ODT?

CLONAZEPAM ODT is a prescription medicine used alone or with other medicines to treat:

- certain types of seizure disorders (epilepsy) in adults and children
- panic disorder with or without fear of open spaces (agoraphobia) in adults

It is not known if CLONAZEPAM ODT is safe or effective in treating panic disorder in children younger than 18 years old.

Do not take CLONAZEPAM ODT if you:

- are allergic to benzodiazepines
- have significant liver disease
- have an eye disease called acute narrow angle glaucoma

Ask your healthcare provider if you are not sure if you have any of the problems listed above.

Before you take CLONAZEPAM ODT, tell your healthcare provider about all your medical conditions, including if you:

- have liver or kidney problems
- have lung problems (respiratory disease)
- have or have had depression, mood problems, or suicidal thoughts or behavior

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

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

How should I take CLONAZEPAM ODT?

- Take CLONAZEPAM ODT exactly as your healthcare provider tells you. CLONAZEPAM is available as a tablet or as an orally disintegrating tablet.
- Do not stop taking CLONAZEPAM ODT without first talking to your healthcare provider. Stopping CLONAZEPAM ODT suddenly can cause serious problems.
- CLONAZEPAM ODT can be taken with or without water.
  - Do not open the pouch until you are ready to take CLONAZEPAM ODT
  - After opening the pouch, peel back the foil on the blister pack.
  - Do not push the orally disintegrating tablet through the foil.
  - After opening the blister pack, with dry hands, take the orally disintegrating tablet and place it in your mouth.
  - The orally disintegrating tablet will melt quickly.
- If you take too much CLONAZEPAM ODT, call your healthcare provider or local Poison Control Center right away.

What should I avoid while taking CLONAZEPAM ODT?

- CLONAZEPAM ODT can slow your thinking and motor skills. Do not drive, operate heavy machinery, or do other dangerous activities until you know how CLONAZEPAM ODT affects you.
- Do not drink alcohol or take other medicines that may make you sleepy or dizzy while taking CLONAZEPAM ODT until you talk to your healthcare provider. When taken with alcohol or medicines that cause sleepiness or dizziness, CLONAZEPAM ODT may make your sleepiness or dizziness worse.

What are the possible side effects of CLONAZEPAM ODT?

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

CLONAZEPAM ODT can also make your seizures happen more often or make them worse. Call your healthcare provider right away if your seizures get worse while taking CLONAZEPAM ODT.

The most common side effects of CLONAZEPAM ODT include:

- Drowsiness
- Problems with walking and coordination
- Dizziness
- Depression
- Fatigue
- Problems with memory

These are not all the possible side effects of CLONAZEPAM ODT.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or Par Pharmaceutical at www.parpharm.com or call 1-800-828-9393.

How should I store CLONAZEPAM ODT?

- Store CLONAZEPAM ODT at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].
- **Keep CLONAZEPAM ODT and all medicines out of the reach of children.**

General Information about the safe and effective use of CLONAZEPAM ODT.

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

For more information, go to www.parpharm.com or call 1-800-828-9393.

What are the ingredients in CLONAZEPAM ODT?

Active ingredient: clonazepam

Inactive ingredients:

- Tablets:
  - 0.125 mg tablets contain aspartame, crospovidone, magnesium stearate, mannitol, silicon dioxide, sorbitol, sodium lauryl sulfate and talc
  - 0.25 mg tablets contain aspartame, crospovidone, magnesium stearate, mannitol, silicon dioxide, sorbitol, sodium lauryl sulfate and talc
  - 0.5 mg tablets contain aspartame, crospovidone, magnesium stearate, mannitol, silicon dioxide, sorbitol, sodium lauryl sulfate and talc
  - 1 mg tablets contain aspartame, crospovidone, magnesium stearate, mannitol, silicon dioxide, sorbitol, sodium lauryl sulfate and talc
  - 2 mg tablets contain aspartame, crospovidone, magnesium stearate, mannitol, silicon dioxide, sorbitol, sodium lauryl sulfate and talc

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

Manufactured by:

PAR PHARMACEUTICAL

Chestnut Ridge, NY 10977

For additional copies of this Medication Guide, visit www.parpharm.com or call 1-800-828-9393

Revised: 09/2016