

Clonazepam (kloe NAZ e pam) Orally Disintegrating Tablets, USP

What is the most important information I should know about clonazepam orally disintegrating tablets?

- **Clonazepam orally disintegrating tablet is 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:

- o shallow or slowed breathing
- o breathing stops (which may lead to the heart stopping)
- o excessive sleepiness (sedation)

Do not drive or operate heavy machinery until you know how taking clonazepam orally disintegrating tablets with opioids affects you.

- **Risk of abuse, misuse, and addiction. There is a risk of abuse, misuse, and addiction with benzodiazepines, including clonazepam orally disintegrating tablet, which can lead to overdose and serious side effects including coma and death.**
 - o **Serious side effects including coma and death have happened in people who have abused or misused benzodiazepines, including clonazepam orally disintegrating 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.**
 - o **You can develop an addiction even if you take clonazepam orally disintegrating tablets exactly as prescribed by your healthcare provider.**
 - o **Take clonazepam orally disintegrating tablets exactly as your healthcare provider prescribed.**
 - o Do not share your clonazepam orally disintegrating tablets with other people.
 - o Keep clonazepam orally disintegrating tablets in a safe place and away from children.
- **Physical dependence and withdrawal reactions.** Clonazepam orally disintegrating tablets can cause physical dependence and withdrawal reactions, especially if you continue to take clonazepam orally disintegrating tablets for several days to several weeks.
 - o **Do not suddenly stop taking clonazepam orally disintegrating tablets.** Stopping clonazepam orally disintegrating 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.**
 - o **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.
 - o 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.
 - o Do not take more clonazepam orally disintegrating tablets than prescribed or take clonazepam orally disintegrating tablets for longer than prescribed.
- **Clonazepam orally disintegrating tablets can make you sleepy or dizzy and can slow your thinking and motor skills. This may get better over time.**
 - o Do not drive, operate heavy machinery, or do other dangerous activities until you know how clonazepam orally disintegrating tablets affects you.
 - o Clonazepam orally disintegrating tablets 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 orally disintegrating tablets until you talk to your healthcare provider.** When taken with alcohol or drugs that cause sleepiness or dizziness, clonazepam orally disintegrating tablets may make your sleepiness or dizziness worse.

- Like other antiepileptic medicines, clonazepam orally disintegrating tablets may cause suicidal thoughts or actions in a very small number of people, about 1 in 500.

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

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

- o Pay attention to any changes, especially sudden changes, in mood, behaviors, thoughts, or feelings.
- o 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 orally disintegrating tablets without first talking to a healthcare provider.**

- o Stopping clonazepam orally disintegrating tablets suddenly can cause serious problems. Stopping clonazepam orally disintegrating tablets suddenly can cause seizures that will not stop (status epilepticus).

• **Clonazepam orally disintegrating tablets may harm your unborn or developing baby.**

- o If you take clonazepam orally disintegrating tablets 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.
- o Children born to mothers receiving benzodiazepine medications (including clonazepam orally disintegrating tablets) late in pregnancy may be at some risk of experiencing breathing problems, feeding problems, hypothermia, and withdrawal symptoms.
- o Tell your healthcare provider right away if you become pregnant while taking clonazepam orally disintegrating tablets. You and your healthcare provider should decide if you will take clonazepam orally disintegrating tablets while you are pregnant.
- o If you become pregnant while taking clonazepam orally disintegrating tablets, 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.
- o Clonazepam can pass into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take clonazepam orally disintegrating tablets. You and your healthcare provider should decide if you will take clonazepam orally disintegrating tablets or breast feed. You should not do both.

What is clonazepam orally disintegrating tablet?

Clonazepam orally disintegrating tablet 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

Clonazepam orally disintegrating tablet is a federally controlled substance (C-IV) because it contains clonazepam that can be abused or lead to dependence. Keep clonazepam orally disintegrating tablets in a safe place to prevent misuse and abuse. Selling or giving away clonazepam orally disintegrating tablets 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.

It is not known if clonazepam orally disintegrating tablet is safe or effective in treating panic disorder in children younger than 18 years old.

Do not take clonazepam orally disintegrating tablet 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 orally disintegrating tablets, 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 orally disintegrating tablets with certain other medicines can cause side effects or affect how well clonazepam orally disintegrating tablets or the other medicines work. Do not start or stop other medicines without talking to your healthcare provider.

How should I take clonazepam orally disintegrating tablets?

- Take clonazepam orally disintegrating tablets exactly as your healthcare provider tells you. Clonazepam is available as a tablet or as an orally disintegrating tablet.
- Do not stop taking clonazepam orally disintegrating tablets without first talking to your healthcare provider. Stopping clonazepam orally disintegrating tablets suddenly can cause serious problems.
- Clonazepam orally disintegrating tablets can be taken with or without water.
 - Do not open the carton until you are ready to take clonazepam orally disintegrating tablets.
 - After opening the carton, 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 orally disintegrating tablets, call your healthcare provider or local Poison Control Center right away.

What should I avoid while taking clonazepam orally disintegrating tablets?

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

What are the possible side effects of clonazepam orally disintegrating tablets?

See “What is the most important information I should know about clonazepam orally disintegrating tablets?”

Clonazepam orally disintegrating tablets 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 orally disintegrating tablets.

The most common side effects of clonazepam orally disintegrating tablets include:

- drowsiness
- dizziness
- fatigue
- problems with walking and coordination
- depression
- problems with memory

These are not all the possible side effects of clonazepam orally disintegrating tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Alembic Pharmaceuticals Limited at 1-866-210-9797.

How should I store clonazepam orally disintegrating tablets?

- Store clonazepam orally disintegrating tablets between 59°F to 86°F (15°C to 30°C)
- **Keep clonazepam orally disintegrating tablets and all medicines out of the reach of children**

General Information about the safe and effective use of clonazepam orally disintegrating tablets

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

For more information call Alembic Pharmaceuticals Limited at 1-866-210-9797.

What are the ingredients in clonazepam orally disintegrating tablets?

Active ingredient: clonazepam

Inactive ingredients: sorbitol, aspartame, sodium lauryl sulfate, crospovidone, mannitol, colloidal silicon dioxide, talc and magnesium stearate

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

Medication Guide available at <http://www.alembicusa.com/medicationguide.aspx> or call 1-866-210-9797.

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