MEDICATION GUIDE

CLONAZEPAM (kloe NAZ e pam)
tablets, for oral use, C-IV

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

- **Clonazepam 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 tablets with opioids affects you.

- **Risk of abuse, misuse, and addiction.** There is a risk of abuse, misuse, and addiction with benzodiazepines, including clonazepam 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 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 tablets as prescribed by your healthcare provider.**
  - o **Take clonazepam tablets exactly as your healthcare provider prescribed.**
  - o **Do not share your clonazepam tablets with other people.**
  - o Keep clonazepam tablets in a safe place and away from children.
- **Physical dependence and withdrawal reactions.** Clonazepam tablets can cause physical dependence and withdrawal reactions.
  - o **Do not suddenly stop taking clonazepam tablets.** Stopping clonazepam 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 tablets than prescribed or take clonazepam tablets for longer than prescribed.
- **Clonazepam 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 tablets affects you.
  - o Clonazepam 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 tablets until you talk to your healthcare provider.** When taken with alcohol or drugs that cause sleepiness or dizziness, clonazepam tablets may make your sleepiness or dizziness worse.
- **Like other antiepileptic drugs, clonazepam 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:

o thoughts about suicide or dying	o attempt to commit suicide	o new or worse depression
o new or worse anxiety	o feeling agitated or restless	o panic attacks
o trouble sleeping (insomnia)	o new or worse irritability	o acting aggressive, being angry, or violent
o acting on dangerous impulses	o an extreme increase in activity and talking (mania)	o 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 tablets without first talking to a healthcare provider.**
- Stopping clonazepam tablets suddenly can cause serious problems. Stopping clonazepam tablets suddenly can cause seizures that will not stop (status epilepticus).

What are clonazepam tablets?

- Clonazepam tablets are prescription medicine used alone or with other medicines to treat:
  - o certain types of seizure disorders (epilepsy) in adults and children
  - o panic disorder with or without fear of open spaces (agoraphobia) in adults

Clonazepam tablet is a federally controlled substance (C-IV) because it contains clonazepam that can be abused or lead to dependence. Keep clonazepam tablets in a safe place to prevent misuse and abuse. Selling or giving away clonazepam 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 tablets are safe or effective in treating panic disorder in children younger than 18 years old.

Who should not take clonazepam tablets?

Do not take clonazepam tablets 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 tablets, tell your healthcare provider if you:

- have liver or kidney problems
- have lung problems (respiratory disease)
- have or have had depression, mood problems, or suicidal thoughts or behavior
- have any other medical problems
- are pregnant or plan to become pregnant. It is not known if clonazepam tablets can harm your unborn baby.

Tell your healthcare provider right away if you become pregnant while taking clonazepam tablets. You and your healthcare provider will decide if you should take clonazepam tablets while you are pregnant.

- o Studies in pregnant animals have shown harmful effects of benzodiazepine medications (including the active ingredient in clonazepam tablets) on the developing fetus.
- o Children born to mothers receiving benzodiazepine medications (including clonazepam tablets) late in pregnancy may be at some risk of experiencing breathing problems, feeding problems, hypothermia, and withdrawal symptoms.
- o If you become pregnant while taking clonazepam 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.

- are breastfeeding or plan to breastfeed. Clonazepam can pass into breast milk. You and your healthcare provider should decide how you will feed your baby while you take clonazepam tablets.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
Taking clonazepam tablets with certain other medicines can cause side effects or affect how well clonazepam tablets or the other medicines work. Do not start or stop other medicines without talking to your healthcare provider.

How should I take clonazepam tablets?

- Take clonazepam tablets exactly as your healthcare provider tells you. If you take clonazepam tablets for seizures, your healthcare provider may change the dose until you are taking the right amount of medicine to control your symptoms.
- Clonazepam is available as a tablet.
- Do not stop taking clonazepam tablets without first talking to your healthcare provider. Stopping clonazepam tablets suddenly can cause serious problems.
- Clonazepam tablets should be taken with water and swallowed whole.
- If you take too much clonazepam tablets, call your healthcare provider or local Poison Control Center right away.

What should I avoid while taking clonazepam tablets?

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

What are the possible side effects of clonazepam tablets?
See "What is the most important information I should know about clonazepam tablets?"
Clonazepam 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 tablets.
The most common side effects of clonazepam tablets include:

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

These are not all the possible side effects of clonazepam tablets. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or contact Advagen Pharma Ltd, at 866-488-0312.

How should I store clonazepam tablets?

- Store clonazepam tablets at 20°C to 25°C (68°F -77°F) [See USP Controlled Room Temperature].
- **Keep clonazepam tablets and all medicines out of the reach of children.**

General Information about the safe and effective use of clonazepam tablets.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use clonazepam tablets for a condition for which it was not prescribed. Do not give clonazepam 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 tablets that is written for health professionals.

For more information, contact Advagen Pharma Ltd, at 866-488-0312.

What are the ingredients in clonazepam tablets?

Active ingredient: clonazepam

Inactive ingredients:

o 0.5 mg tablets contain lactose monohydrate, polyethylene glycol, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, FD & C Yellow 6 Al Lake, D & C Yellow 10 Al Lake

o 1 mg tablets contain lactose monohydrate, polyethylene glycol, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, FD & C Blue 1 Al lake and FD & C Blue 2 Al lake

o 2 mg tablets contain lactose monohydrate, polyethylene glycol, microcrystalline cellulose, croscarmellose sodium and magnesium stearate

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

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