

# MEDICATION GUIDE

## CLORAZEPATE

### DIPOTASSIUM TABLETS, USP



Read this Medication Guide before you start taking clorazepate dipotassium 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.

**What is the most important information I should know about clorazepate dipotassium tablets?**

**Do not stop taking clorazepate dipotassium tablets without first talking to your healthcare provider.**

Stopping clorazepate dipotassium tablets suddenly can cause serious problems.

**Clorazepate dipotassium tablets can cause serious side effects, including:**

**1. Clorazepate dipotassium tablets 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 clorazepate dipotassium tablets affect you.
- Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking clorazepate dipotassium tablets without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, clorazepate dipotassium tablets may make your sleepiness or dizziness much worse.

**2. Clorazepate dipotassium tablets can cause abuse and dependence.**

- Do not stop taking clorazepate dipotassium tablets all of a sudden. Stopping clorazepate dipotassium tablets 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 doctor about slowly stopping clorazepate dipotassium tablets to avoid getting sick with 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.

**Clorazepate dipotassium tablets are a federally controlled substance (C-IV) because it can be abused or lead to dependence. Keep clorazepate dipotassium tablets in a safe place to prevent misuse and abuse. Selling or giving away clorazepate dipotassium 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.**

**3. Clorazepate dipotassium tablets may harm your unborn or developing baby.**

Medicines like clorazepate dipotassium tablets can cause birth defects. Talk with your healthcare provider if you are pregnant or plan to become pregnant. Tell your healthcare provider right away if you become

pregnant while taking clorazepate dipotassium tablets. You and your healthcare provider should decide if you will take clorazepate dipotassium tablets while 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.

- If you become pregnant while taking clorazepate dipotassium 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.
- Clorazepate dipotassium can pass into breast milk. Talk to your healthcare provider about the best way to feed your baby if you take clorazepate dipotassium tablets. You and your healthcare provider should decide if you will take clorazepate dipotassium tablets or breast-feed. You should not do both.

**4. Like other antiepileptic drugs, clorazepate dipotassium 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
- attempts 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.

**Do not stop clorazepate dipotassium tablets without first talking to a healthcare provider.**

Stopping clorazepate dipotassium tablets suddenly can cause serious problems.

Stopping a seizure medicine suddenly in a patient who has epilepsy can cause seizures that will not stop (status epilepticus).

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.

**What are clorazepate dipotassium tablets?**

Clorazepate dipotassium tablets are a prescription medicine used:

- to treat anxiety disorders
- with other medicines to treat partial seizures
- to treat the symptoms of sudden alcohol withdrawal

### Who should not take clorazepate dipotassium tablets?

Do not take clorazepate dipotassium tablets if you:

- are allergic to clorazepate dipotassium or any of the ingredients in clorazepate dipotassium tablets. See the end of this Medication Guide for a complete list of ingredients in clorazepate dipotassium tablets.
- have an eye disease called acute narrow angle glaucoma.

### What should I tell my healthcare provider before taking clorazepate dipotassium tablets?

Before you take clorazepate dipotassium tablets, tell your healthcare provider if you:

- have liver or kidney problems
- have or have had depression, mood problems, or suicidal thoughts or behavior
- have a history of abnormal thinking and behavior (psychotic reactions)
- have any other medical conditions

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

Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.

### How should I take clorazepate dipotassium tablets?

- Take clorazepate dipotassium tablets exactly as prescribed. Your healthcare provider will tell you how much clorazepate dipotassium tablets to take.
- Your healthcare provider may change your dose. Do not change your dose of clorazepate dipotassium tablets without talking to your healthcare provider.
- Do not stop taking clorazepate dipotassium tablets without first talking to your healthcare provider. Stopping clorazepate dipotassium tablets suddenly can cause serious problems.

If you take too much clorazepate dipotassium tablets, call your healthcare provider or local Poison Control Center right away.

### What are the possible side effects of clorazepate dipotassium tablets?

See “What is the most important information I should know about clorazepate dipotassium tablets?”.

The most common side effects of clorazepate dipotassium tablets include:

- drowsiness
- dizziness
- upset stomach
- blurred vision
- dry mouth
- confusion

These are not all the possible side effects of clorazepate dipotassium tablets. For more information ask your healthcare provider or pharmacist. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

**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 clorazepate dipotassium tablets?

- Store clorazepate dipotassium tablets between 20° to 25°C (68° to 77°F).
- Keep clorazepate dipotassium tablets in a tightly closed container.
- Keep clorazepate dipotassium tablets out of the light.
- Keep clorazepate dipotassium tablets dry.

**Keep clorazepate dipotassium tablets and all medicines away from children.**

### General Information about Clorazepate Dipotassium Tablets

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use clorazepate dipotassium tablets for a condition for which it was not prescribed. Do not give clorazepate dipotassium tablets to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about clorazepate dipotassium tablets. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about clorazepate dipotassium tablets that is written for health professionals.

For more information about clorazepate dipotassium tablets, contact Mylan Pharmaceuticals Inc. toll free at 1-877-446-3679 (1-877-4-INFO-RX).

### What are the ingredients in clorazepate dipotassium tablets, USP?

Active ingredient: clorazepate dipotassium, USP

Inactive ingredients: croscarmellose sodium, magnesium oxide, magnesium stearate, microcrystalline cellulose, potassium carbonate, sodium chloride, sodium lauryl sulfate and the following coloring agents:

3.75 mg - FD&C Blue No. 2 Aluminum Lake

7.5 mg - FD&C Yellow No. 6 Aluminum Lake

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



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