

MEDICATION GUIDE

Clorazepate Dipotassium Tablets, USP (klor az' e pate dye" poe tas' ee um)

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

- **Clorazepate dipotassium 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:**
 - shallow or slowed breathing
 - breathing stops (which may lead to the heart stopping)
 - excessive sleepiness (sedation)

Do not drive or operate heavy machinery until you know how taking clorazepate dipotassium tablets and opioids affects you.

- **Risk of abuse, misuse, and addiction.** There is a risk of abuse, misuse, and addiction with benzodiazepines including clorazepate dipotassium tablets which can lead to overdose and serious side effects including coma and death.
 - **Serious side effects including coma and death have happened in people who have abused or misused benzodiazepines, including clorazepate dipotassium 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.**
 - You can develop an addiction even if you take clorazepate dipotassium tablets as prescribed by your healthcare provider
 - **Take clorazepate dipotassium tablets exactly as your healthcare provider prescribed.**
 - Do not share your clorazepate dipotassium tablets with other people.
 - Keep clorazepate dipotassium tablets in a safe place and away from children.
- **Physical dependence and withdrawal reactions.** Clorazepate dipotassium tablets can cause physical dependence and withdrawal reactions,.
 - **Do not suddenly stop taking clorazepate dipotassium tablets.** Stopping clorazepate dipotassium 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.**
 - **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.
 - 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.
 - **Do not take more clorazepate dipotassium tablets than prescribed or take clorazepate dipotassium tablets for longer than prescribed.**

- **Like other antiepileptic medicines, 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:

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| • thoughts about suicide or dying | • feeling agitated or restless | • acting aggressive, being angry, or violent |
| • attempts to commit suicide | • panic attacks | • acting on dangerous impulses |
| • new or worse depression | • trouble sleeping (insomnia) | • an extreme increase in activity and talking (mania) |
| • new or worse anxiety | • new or worse irritability | • 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.

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

clorazepate dipotassium tablets is a federally controlled substance (C-IV) because it contains clorazepate dipotassium that 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.

It is not known if clorazepate dipotassium tablets are safe and effective in children less than 9 years of age.

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.

Before you take clorazepate dipotassium tablets, tell your healthcare provider about all your medical conditions, including 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)
- are pregnant or plan to become pregnant.
 - Taking clorazepate dipotassium tablets late in pregnancy may cause your baby to have symptoms of sedation (breathing problems, sluggishness, low muscle tone), and/or withdrawal symptoms (jitteriness, irritability, restlessness, shaking, excessive crying, feeding problems).

- Tell your healthcare provider right away if you become pregnant or think you are pregnant during treatment with clorazepate dipotassium tablets.
- There is a pregnancy registry for women who take clorazepate dipotassium tablets during pregnancy. The purpose of the registry is to collect information about the health of you and your baby. If you become pregnant during treatment with clorazepate dipotassium tablets, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychiatric Medications. You can register by calling 1866-961-2388-or visiting <https://womensmentalhealth.org/pregnancyregistry/>.
- are breastfeeding or plan to breastfeed. Clorazepate dipotassium passes into breast milk.
- Talk to your healthcare provider about the best way to feed your baby if you take clorazepate dipotassium tablets.
- Breastfeeding is not recommended during treatment with clorazepate dipotassium tablets.

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

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

How should I take clorazepate dipotassium tablets?

- Take clorazepate dipotassium tablets exactly as your healthcare provider tells you to take it. Your healthcare provider will tell you how much clorazepate dipotassium tablets to take and when to take it.
- Your healthcare provider may change your dose if needed. 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 go to the nearest hospital emergency room right away.

What are the possible side effects of clorazepate dipotassium tablets?

Clorazepate dipotassium tablets may cause serious side effects, including: See “What is the most important information I should know about clorazepate dipotassium tablets?”

- **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 affects 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.

The most common side effects of clorazepate dipotassium tablets include:

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| • drowsiness | • upset stomach | • dry mouth |
| • dizziness | • blurred vision | |

These are not all the possible side effects of clorazepate dipotassium tablets. For more information, ask your healthcare provider or pharmacist.

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 at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep clorazepate dipotassium tablets in a tightly closed container, dry, and out of the light.
- **Keep clorazepate dipotassium tablets and all medicines out of the reach of children.**

General Information about the safe and effective use of 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. You can ask your pharmacist or healthcare provider for information about clorazepate dipotassium tablets that is written for health professionals.

What are the ingredients in clorazepate dipotassium tablets?

Active ingredient: clorazepate dipotassium

Inactive ingredients: colloidal silicon dioxide, FD&C Blue No. 2 Aluminum Lake (3.75 mg only), FD&C Red No. 40 Aluminum Lake (15 mg only), FD&C Yellow No. 6 Aluminum Lake (7.5 mg only), magnesium oxide, magnesium stearate, microcrystalline cellulose, potassium carbonate, and potassium chloride.

APOTEX INC.**Clorazepate Dipotassium Tablets, USP****3.75 mg, 7.5 mg and 15 mg****Manufactured by:**

CorePharma, LLC
215 Wood Avenue,
Middlesex, NJ 08846, USA

Manufactured for:

Apotex Corp.
Weston, Florida
USA 33326

For more information, call Apotex Corp. at 1-800-706-5575 or go to www.apotex.com.

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

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