

Medication Guide

Chlordiazepoxide and Amitriptyline Hydrochloride Tablets, USP (klor" dye az" e pox' ide am" i trip' ti leen hye" droe klor' ide)



What is the most important information I should know about chlordiazepoxide and amitriptyline hydrochloride tablets?

- **This medicine contains chlordiazepoxide. Chlordiazepoxide is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma and death.**
- **Suicidal thoughts or actions.** Chlordiazepoxide and amitriptyline hydrochloride tablets and other antidepressant medicines may increase suicidal thoughts or actions in some children, teenagers, or young adults (18 to 24 years of age) **within the first few months of treatment or when the dose is changed.**
- **Depression or other serious mental illnesses are the most important cause of suicidal thoughts or actions.**
- **How can I watch for and try to prevent suicidal thoughts and actions?**
 - Pay particular attention to such changes when chlordiazepoxide and amitriptyline hydrochloride tablets are started or when the dose is changed.
 - Keep all follow-up visits with your healthcare provider and call between visits if you are worried about symptoms.
 - **Call your healthcare provider right away if you have any of the following symptoms, especially if they are new, worse, or worry you:**
 - attempts to commit suicide
 - acting on dangerous impulses
 - acting aggressive or violent
 - thoughts about suicide or dying
 - new or worse depression
 - new or worse anxiety or panic attacks
 - feeling agitated, restless, angry or irritable
 - trouble sleeping (insomnia)
 - an increase in activity or talking more than what is normal for you (mania)
 - other unusual changes in behavior or mood
- **Chlordiazepoxide and amitriptyline hydrochloride 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 chlordiazepoxide and amitriptyline hydrochloride tablets affect you.
 - Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking chlordiazepoxide and amitriptyline hydrochloride tablets without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, chlordiazepoxide and amitriptyline hydrochloride tablets may make your sleepiness or dizziness much worse.
- Do not take more chlordiazepoxide and amitriptyline hydrochloride tablets than prescribed.

What are chlordiazepoxide and amitriptyline hydrochloride tablets?

- Chlordiazepoxide and amitriptyline hydrochloride tablets are a prescription medicine used to treat moderate to severe depression that can happen with moderate to severe anxiety.
- **Chlordiazepoxide and amitriptyline hydrochloride tablets are a federal controlled substance (C-IV) because it can be abused or lead to dependence.** Keep chlordiazepoxide and amitriptyline hydrochloride tablets in a safe place to prevent misuse and abuse. Selling or giving away chlordiazepoxide and amitriptyline hydrochloride 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 chlordiazepoxide and amitriptyline hydrochloride tablets are safe and effective in children.

Do not take chlordiazepoxide and amitriptyline hydrochloride tablets if you:

- are allergic to benzodiazepines or tricyclic antidepressant medicines
- take a medicine called a Monoamine Oxidase Inhibitor (MAOI). Ask your healthcare provider or pharmacist if you are not sure if you take an MAOI.
- are recovering from a heart attack (myocardial infarction)

Before you take chlordiazepoxide and amitriptyline hydrochloride tablets, tell your healthcare provider about all of your medical conditions, including if you:

- have bipolar disorder (manic depression) or mania
- have a history of drug or alcohol abuse or addiction
- have eye problems
- have problems urinating or emptying your bladder
- have kidney or liver problems
- have or had heart problems, including heart attack or a stroke
- have or have had seizures
- have a thyroid problem
- plan to have surgery
- receive electroconvulsive therapy (ECT)
- are pregnant or plan to become pregnant. Chlordiazepoxide and amitriptyline hydrochloride tablets may harm your unborn baby. Avoid taking chlordiazepoxide and amitriptyline hydrochloride tablets during the first trimester of pregnancy. Tell your healthcare provider right away if you become pregnant during treatment with chlordiazepoxide and amitriptyline hydrochloride tablets.
- are breastfeeding or plan to breastfeed. It is not known if chlordiazepoxide and amitriptyline hydrochloride pass into your breast milk. You should not breastfeed while taking chlordiazepoxide and amitriptyline hydrochloride tablets. Talk to your healthcare provider about the best way to feed your baby if you take chlordiazepoxide and amitriptyline hydrochloride tablets.

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

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

How should I take chlordiazepoxide and amitriptyline hydrochloride tablets?

- Take chlordiazepoxide and amitriptyline hydrochloride tablets exactly as your healthcare provider tells you to take it.
- If you take too many chlordiazepoxide and amitriptyline hydrochloride tablets, call your healthcare provider or go to the nearest emergency room right away.

What are the possible side effects of chlordiazepoxide and amitriptyline hydrochloride tablets?

Chlordiazepoxide and amitriptyline hydrochloride tablets may cause serious side effects, including:

- **See “What is the most important information I should know about chlordiazepoxide and amitriptyline hydrochloride tablets?”**
- **Withdrawal symptoms.** You may have withdrawal symptoms if you stop taking chlordiazepoxide and amitriptyline hydrochloride tablets suddenly. Withdrawal symptoms can be serious and include seizures. Mild withdrawal symptoms include a depressed mood and trouble sleeping. Talk to your healthcare provider about slowly stopping chlordiazepoxide and amitriptyline hydrochloride tablets to avoid withdrawal symptoms.
- **Abuse and dependence.** Taking chlordiazepoxide and amitriptyline hydrochloride tablets can cause physical and psychological dependence. Physical and psychological dependence is not the same as drug addiction. Your healthcare provider can tell you more about the differences between physical and psychological dependence and drug addiction.

The most common side effects of chlordiazepoxide and amitriptyline hydrochloride tablets include:

- drowsiness
- constipation
- dizziness
- dry mouth
- blurred vision
- bloating

These are not all the possible side effects of chlordiazepoxide and amitriptyline hydrochloride tablets. **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 chlordiazepoxide and amitriptyline hydrochloride tablets?

- Store at 20° to 25°C (68° to 77°F). Store in a dry place.
- Keep chlordiazepoxide and amitriptyline hydrochloride tablets in a tightly closed, child-resistant container and out of the light.
- **Keep chlordiazepoxide and amitriptyline hydrochloride tablets and all medicines out of the reach of children.**

General information about the safe and effective use of chlordiazepoxide and amitriptyline hydrochloride tablets.

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

What are the ingredients in chlordiazepoxide and amitriptyline hydrochloride tablets?

Active ingredients: chlordiazepoxide, amitriptyline hydrochloride

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, pregelatinized starch (corn), sodium lauryl sulfate, and titanium dioxide. In addition, the 5 mg/12.5 mg tablets also contain D&C Yellow No. 10 Aluminum Lake, FD&C Blue No. 1 Aluminum Lake and FD&C Yellow No. 6 Aluminum Lake and the 10 mg/25 mg tablets also contain calcium sulfate and talc.

Manufactured by: Mylan Pharmaceuticals Inc., Morgantown, WV 26505 U.S.A.

For more information, call Mylan Pharmaceuticals Inc. at 1-877-446-3679 (1-877-4-INFO-RX).

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



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