Medication Guide

Medication Guide Chlordiazepoxide Hydrochloride
(klor″ dye az″ e pox′ ide hye″droe klor′ ide)Capsules, USP C-IV

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

- **Chlordiazepoxide Hydrochloride is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system depressants (CNS) (including street drugs) can causesevere 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 chlordiazepoxide hydrochloride with opioids affects you.

- **Risk of abuse, misuse, and addiction.** There is a risk of abuse, misuse, and addiction with benzodiazepines, including chlordiazepoxide hydrochloride, 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 chlordiazepoxide hydrochloride. 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 chlordiazepoxide hydrochloride exactly as prescribed by your healthcare provider.**
  - **Take chlordiazepoxide hydrochloride exactly as your healthcare provider prescribed.**
  - Do not share your chlordiazepoxide hydrochloride with other people.
  - Keep chlordiazepoxide hydrochloride in a safe place and away from children.
- **Physical dependence and withdrawal reactions.** Chlordiazepoxide Hydrochloride can cause physical dependence and withdrawal reactions, especially if you continue to take chlordiazepoxide hydrochloride for several days to several weeks.
  - **Do not suddenly stop taking chlordiazepoxide hydrochloride.** Stopping chlordiazepoxide hydrochloride 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 chlordiazepoxide hydrochloride than prescribed or take chlordiazepoxide hydrochloride for longer than prescribed.

What is chlordiazepoxide hydrochloride?

- Chlordiazepoxide Hydrochloride is a prescription medicine used:
  - to treat anxiety disorders
  - for the short-term relief of the symptoms of anxiety
  - to treat withdrawal symptoms of acute alcoholism
  - preoperatively to treat apprehension and anxiety
- **Chlordiazepoxide Hydrochloride is a federal controlled substance (C-IV) because it contains chlordiazepoxide that can be abused or lead to dependence.** Keep chlordiazepoxide hydrochloride in a safe place to prevent misuse and abuse. Selling or giving away chlordiazepoxide may harm others, and is against the law. Tell your healthcare provider if you have abused or been dependent on alcohol, prescription medicines or street drugs.
- It is not known if chlordiazepoxide is safe and effective in children under 6 years of age.
- It is not known if chlordiazepoxide is safe and effective for use for longer than 4 months.

Do not take chlordiazepoxide hydrochloride if you are allergic to chlordiazepoxide or to any of the ingredients in chlordiazepoxide hydrochloride capsules. See the end of this Medication Guide for a complete list of ingredients inchlordiazepoxide hydrochloride capsules.

Before you take chlordiazepoxide hydrochloride, tell your healthcare provider about all of your medicalconditions, including if you:

- have or have had depression, mood problems, or suicidal thoughts or behavior
- have a history of drug or alcohol abuse or addiction
- have liver or kidney problems
- are pregnant or plan to become pregnant.
  - Taking chlordiazepoxide hydrochloride 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 chlordiazepoxide hydrochloride.
  - There is a pregnancy registry for women who take chlordiazepoxide hydrochloride 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 chlordiazepoxide hydrochloride, talk to your healthcare provider about registering with the National Pregnancy Registry for Psychiatric Medications. You can register by calling 1-866-961-2388 or visiting https://womansmentalhealth.org/pregnancyregistry/.
- are breastfeeding or plan to breastfeed. Chlordiazepoxide hydrochloride may pass into your breast milk.
  - Talk to your healthcare provider about the best way to feed your baby if you take chlordiazepoxide hydrochloride.
  - Breastfeeding is not recommended during treatment with chlordiazepoxide hydrochloride.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-countermedicines, vitamins, and herbal supplements.
Taking chlordiazepoxide hydrochloride with certain other medicines can cause side effects or affect how well chlordiazepoxide hydrochloride orthe other medicines work.
Ask your healthcare provider if you are not sure if you are taking any of these medicines. Your healthcare providercan tell you if it is safe to take chlordiazepoxide hydrochloride with your other medicines.

Do not start or stop any other medicines during treatment with chlordiazepoxide hydrochloride without talking to your healthcare provider first. Stopping chlordiazepoxide hydrochloride suddenly may cause you to have serious sideeffects. See, **"What are the possible side effects of chlordiazepoxide hydrochloride?"** Know the medicines you take. Keep a list of them to show to your healthcare provider and pharmacist when you geta new medicine.

How should I take chlordiazepoxide?

- Take chlordiazepoxide exactly as your healthcare provider tells you to take it.
- If you take too much chlordiazepoxide hydrochloride, call your healthcare provider or go to the nearest hospital emergencyroom right away.

What are the possible side effects of chlordiazepoxide hydrochloride? Chlordiazepoxide hydrochloride may cause serious side effects, including:

- **See "What is the most important information I should know about chlordiazepoxide hydrochloride?"**
- **Chlordiazepoxide Hydrochloride can make you sleepy or dizzy and can slow your thinking and motorskills.**
  - Do not drive, operate heavy machinery, or do other dangerous activities until you know how chlordiazepoxide hydrochloride affects you.
  - Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking chlordiazepoxide hydrochloride without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, chlordiazepoxide hydrochloride may make your sleepiness or dizziness much worse.

The most common side effects of chlordiazepoxide hydrochloride include:

- drowsiness
- loss of control of body movements (ataxia)
- confusion

These are not all the possible side effects of chlordiazepoxide hydrochloride. 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 hydrochloride?

- Store chlordiazepoxide hydrochloride at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep chlordiazepoxide hydrochloride in a tightly closed container and out of the light.

Keep chlordiazepoxide hydrochloride and all medicines out of the reach of children.

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

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use chlordiazepoxide hydrochloride for a condition for which it was not prescribed. Do not give chlordiazepoxide hydrochloride to other people, even if they have the same symptoms that you have. It may harm them. You can askyour pharmacist or healthcare provider for information about chlordiazepoxide hydrochloride that is written for health professionals.

What are the ingredients in chlordiazepoxide hydrochloride?

Active ingredient: chlordiazepoxide hydrochloride

Inactive ingredients:

5 mg: colloidal silicon dioxide, corn starch, D & C Yellow #10, FD & C Blue #1, FD & C Yellow #6, gelatin, lactose monohydrate, talc, titanium dioxide, shellac, black iron oxide, and propylene glycol.

10 mg**:** colloidal silicon dioxide, corn starch, D & C Yellow #10, FD & C Blue #1, FD & C Red #3, FD & C Yellow #6, gelatin, lactose monohydrate, talc, titanium dioxide, shellac, propylene glycol, and simethicone.

25 mg: colloidal silicon dioxide, corn starch, D & C Yellow #10, FD & C Blue #1, gelatin, lactose monohydrate, talc, titanium dioxide, shellac, black iron oxide, and propylene glycol.

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Middlesex, NJ 08846

Manufactured for:
Chartwell RX, LLC
Congers, NY 10920

For more information, contact Chartwell RX, LLC. at 1-845-232-1683

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