

## MEDICATION GUIDE

### Chlordiazepoxide Hydrochloride and Clidinium Bromide Capsules

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- **What is the most important information I should know about chlordiazepoxide hydrochloride and clidinium bromide capsules? Do not stop taking chlordiazepoxide hydrochloride and clidinium bromide capsules without first talking to your healthcare provider.** Stopping chlordiazepoxide hydrochloride and clidinium bromide capsules suddenly can cause serious side effects.
- **Taking chlordiazepoxide hydrochloride and clidinium bromide capsules with opioid medicines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma and death.**
- Do not drive, operate heavy machinery, or do other dangerous activities until you know how chlordiazepoxide hydrochloride and clidinium bromide capsules affects you.
- Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking chlordiazepoxide hydrochloride and clidinium bromide capsules without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, chlordiazepoxide hydrochloride and clidinium bromide capsules may make your sleepiness or dizziness much worse.
- **chlordiazepoxide hydrochloride and clidinium bromide capsules can cause abuse and dependence.**
- Do not stop taking chlordiazepoxide hydrochloride and clidinium bromide capsules all of a sudden. Stopping chlordiazepoxide hydrochloride and clidinium bromide capsules suddenly can cause seizures, shaking, stomach and muscle cramps, vomiting and sweating.
- Physical dependence is not the same as drug addiction. Your healthcare provider can tell you more about

#### **What are chlordiazepoxide hydrochloride and clidinium bromide capsules?**

- Chlordiazepoxide hydrochloride and clidinium bromide capsules are a prescription medicine that are used with other therapies for the treatment of:
  - stomach (peptic) ulcers
  - irritable bowel syndrome (IBS)
  - inflammation of the colon called acute enterocolitis
- chlordiazepoxide hydrochloride and clidinium bromide capsules contains the medicines chlordiazepoxide HCl and clidinium bromide.
- **chlordiazepoxide hydrochloride and clidinium bromide capsules can be abused or lead to dependence.** Keep chlordiazepoxide hydrochloride and clidinium bromide capsules in a safe place to prevent misuse and abuse. Selling or giving away chlordiazepoxide hydrochloride and clidinium bromide capsules may harm others. Tell

your healthcare provider if you have abused or been dependent on alcohol, prescription medicines or street drugs.

- It is not known if chlordiazepoxide hydrochloride and clidinium bromide capsules are safe and effective in children.

**Do not take chlordiazepoxide hydrochloride and clidinium bromide capsules if you:**

- have glaucoma
- have an enlarged prostate
- have a blockage of your bladder that causes problems with urination
- are allergic to chlordiazepoxide hydrochloride or clidinium bromide

**Before you take chlordiazepoxide hydrochloride and clidinium bromide capsules, tell your healthcare provider about all of your medical conditions, including if you:**

- have eye problems
- have problems urinating or emptying your bladder
- have coordination problems
- have kidney or liver problems
- have a history of depression, mental illness, or suicidal thoughts
- have a history of drug or alcohol abuse or addiction
- have bleeding problems
- are pregnant or plan to become pregnant. Chlordiazepoxide hydrochloride and clidinium bromide capsules may harm your unborn baby. Avoid taking chlordiazepoxide hydrochloride and clidinium bromide capsules during the first trimester of pregnancy. Tell your healthcare provider right away if you become pregnant during treatment with chlordiazepoxide hydrochloride and clidinium bromide capsules
- are breastfeeding or plan to breastfeed. Chlordiazepoxide hydrochloride and clidinium bromide capsules may pass through your breast milk and may harm your baby. Talk to your healthcare provider about the best way to feed your baby if you take chlordiazepoxide hydrochloride and clidinium bromide capsules. Chlordiazepoxide hydrochloride and clidinium bromide capsules may decrease the amount of breast milk your body makes.

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

Taking chlordiazepoxide hydrochloride and clidinium bromide capsules with certain other medicines can cause side effects or affect how well chlordiazepoxide hydrochloride and clidinium bromide capsules or the other medicines work.

Do not start or stop other medicines without talking to your healthcare provider.

Especially tell your healthcare provider if you:

- take a monoamine oxidase inhibitor (MAOI) medicine or an anti-psychotic medicine called phenothiazine.

**How should I take chlordiazepoxide hydrochloride and clidinium bromide capsules?**

- Take chlordiazepoxide hydrochloride and clidinium bromide capsules exactly as your healthcare provider tells you to take it.
- Your healthcare provider may change your dose of chlordiazepoxide hydrochloride and clidinium bromide capsules if needed. Do not change your dose of chlordiazepoxide hydrochloride and clidinium bromide capsules or suddenly stop taking chlordiazepoxide hydrochloride and clidinium bromide capsules without talking with your healthcare provider.
- If you take too much chlordiazepoxide hydrochloride and clidinium bromide capsules, call your healthcare provider or go to the nearest hospital emergency room right away.

### **What are the possible side effects of chlordiazepoxide hydrochloride and clidinium bromide capsules?**

**Chlordiazepoxide hydrochloride and clidinium bromide capsules may cause serious side effects, including: See “What is the most important information I should know about chlordiazepoxide hydrochloride and clidinium bromide capsules?”**

**The most common side effects of chlordiazepoxide hydrochloride and clidinium bromide capsules include:**

- dry mouth
- blurred vision
- nausea
- constipation
- skin problems
- swelling
- irregular menstrual (periods) cycles
- increased and decreased desire for sex (libido)
- problems starting to urinate
- drowsiness, coordination problems, and confusion may happen, especially in people who are elderly or weak

These are not all the possible side effects of chlordiazepoxide hydrochloride and clidinium bromide capsules

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 and clidinium bromide capsules?**

- Store chlordiazepoxide hydrochloride and clidinium bromide capsules at room temperature 77°F (25°C).
- **Keep chlordiazepoxide hydrochloride and clidinium bromide capsules and all medicines out of the reach of children.**

### **General information about the safe and effective use of chlordiazepoxide hydrochloride and clidinium bromide capsules.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use chlordiazepoxide hydrochloride and clidinium bromide capsules for a condition for

which it was not prescribed. Do not give chlordiazepoxide hydrochloride and clidinium bromide capsules 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 hydrochloride and clidinium bromide capsules that is written for health professionals.

**What are the ingredients in chlordiazepoxide hydrochloride and clidinium bromide capsules?**

**Active ingredient:** chlordiazepoxide hydrochloride and clidinium bromide

**Inactive ingredients:** corn starch, lactose monohydrate, and talc. Gelatin capsule shells may contain titanium dioxide and sodium lauryl sulfate with the following dye systems: D&C Yellow No. 10, FD&C Green No. 3. The imprinting ink contains ammonia solution, black iron oxide, potassium hydroxide, propylene glycol, and shellac.

Manufactured for:

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

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

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