

**CHLORDIAZEPOXIDE- chlordiazepoxide capsule, gelatin coated
DIRECT RX**

CHLORIDIAZEPOXIDE 25mg

DESCRIPTION:

-

CLINICAL PHARMACOLOGY:

-

INDICATIONS AND USAGE:

-

CONTRAINDICATIONS:

-

WARNINGS:

-

PRECAUTIONS:

-

ADVERSE REACTIONS:

-

DRUG ABUSE AND DEPENDENCE:

-

OVERDOSAGE:

-

DOSAGE AND ADMINISTRATION:

-

STORAGE AND HANDLING

-

Chlordiazepoxide Hydrochloride
Capsules, USP C-IV

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

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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.

- Chlordiazepoxide can make you sleepy or dizzy, and can slow your thinking and motor skills.

- o Do not drive, operate heavy machinery, or do other dangerous activities until you know how chlordiazepoxide affects you.

- o Do not drink alcohol or take other drugs that may make you sleepy or dizzy while taking chlordiazepoxide without first talking to your healthcare provider. When taken with alcohol or drugs that cause sleepiness or dizziness, chlordiazepoxide may make your sleepiness or dizziness much worse.

- o Do not take more chlordiazepoxide than prescribed.

What is chlordiazepoxide?

- Chlordiazepoxide is a prescription medicine used:

- o to treat anxiety disorders

- o for the short-term relief of the symptoms of anxiety

- o to treat withdrawal symptoms of acute alcoholism

- o preoperatively to treat apprehension and anxiety

- Chlordiazepoxide is a federal controlled substance (C-IV) because it can be abused or lead to dependence. Keep chlordiazepoxide 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 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 in Chlordiazepoxide Hydrochloride Capsules.

Before you take chlordiazepoxide Hydrochloride, tell your healthcare provider about all of your medical conditions, 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. Chlordiazepoxide may harm your unborn baby. You and your healthcare provider should decide if you should take chlordiazepoxide while you are pregnant

- are breastfeeding or plan to breastfeed. Chlordiazepoxide may pass into 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 .

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

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

How should I take chlordiazepoxide ?

- Take chlordiazepoxide exactly as your healthcare provider tells you to take it. Your healthcare provider will tell you how much chlordiazepoxide to take and when to take it.

- If you take too much chlordiazepoxide, call your healthcare provider or go to the nearest hospital emergency room right away.

What should I avoid while taking chlordiazepoxide ?

- Chlordiazepoxide can cause you to be drowsy. Do not drive a car or operate heavy machinery until you know how chlordiazepoxide affects you.

- You should not drink alcohol while taking chlordiazepoxide. Drinking alcohol can increase your chances of having serious side effects.

What are the possible side effects of chlordiazepoxide ?

Chlordiazepoxide may cause serious side effects, including:

- See “What is the most important information I should know about chlordiazepoxide ?”

- Abuse and dependence. Taking chlordiazepoxide 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.

- Withdrawal symptoms. You may have withdrawal symptoms if you stop taking chlordiazepoxide 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 to avoid withdrawal symptoms.

The most common side effects of chlordiazepoxide include:

- drowsiness

- loss of control of body movements (ataxia)

- confusion

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

- Store Chlordiazepoxide Hydrochloride Capsules at room temperature between 68°F to 77°F (20°C to 25°C).

• Keep Chlordiazepoxide Hydrochloride Capsules in a tightly closed container and out of the light.

• Keep Chlordiazepoxide Hydrochloride Capsules and all medicines out of the reach of children.

General information about the safe and effective use of Chlordiazepoxide Hydrochloride Capsules.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Chlordiazepoxide Hydrochloride Capsules for a condition for which it was not prescribed. Do not give Chlordiazepoxide Hydrochloride 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 Capsules that is written for health professionals.

What are the ingredients in Chlordiazepoxide Hydrochloride Capsules?

Active ingredient: chlordiazepoxide hydrochloride

Inactive ingredients: FD&C Yellow No. 6 plus D&C Yellow No. 10 and either FD&C Blue No. 1 or FD&C Green No. 3 , D&C Yellow No. 10 and either FD&C Blue No. 1 plus FD&C Red No. 3 or FD&C Green No. 3 plus FD&C Red No. 40 , D&C Yellow No. 10 and either FD&C Green No. 3 or FD&C Blue No. 1 (10mg only), FD&C yellow #6 (10mg only), gelatin, hydrogenated vegetable oil, lactose anhydrous, methylparaben, microcrystalline cellulose, propylparaben, silicon dioxide, sodium lauryl sulfate and titanium dioxide

Distributed by:

Solco Healthcare U.S., LLC

Cranbury, NJ 08512

This Medication Guide has been approved by the U.S. Food and Drug Administration Issued: 12/2017

PRINCIPAL DISPLAY PANEL

D CHLORDIAZEPOXIDE C - IV
25mg 20 Caps

Generic For: **LIBRIUM**
Each capsule contains 25mg of chlordiazepoxide hydrochloride USP

Lot# 711-20 Discard After: 10/17

Packaged and Distributed By: **DIRECT Rx** Alpharetta, GA 30005

M CHLORDIAZEPOXIDE C - IV 25mg
NDC 61919-711-20 20 Ca
Lot Exp Date 10/17
Mfg NDC 43547-253-10

CHLORDIAZEPOXIDE C - IV 25mg
NDC 61919-711-20 20 Ca
Lot Exp Date 10/17
Mfg NDC 43547-253-10

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CHLORDIAZEPOXIDE C - IV 25mg
NDC 61919-711-20 20 Ca
Lot Exp Date 10/17
Mfg NDC 43547-253-10

Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.

RX ONLY - KEEP OUT OF REACH OF CHILDREN

Dosage: See package insert. Store between 68-77 degrees F.

May cause drowsiness or dizziness. **ALCOHOL** may intensify this effect. Use care when operating dangerous machinery. Medication should be taken with plenty of water.

NDC 61919-711-20

4/1/10

D CHLORDIAZEPOXIDE C-IV
25mg 30 Caps

Generic For: **LIBRIUM**
Each capsule contains 25mg of chlordiazepoxide hydrochloride USP

Lot# Prod# 593-30 Discard After: 11/20
Packaged and Distributed By: **DIRECT B** Alpharetta, GA 30005

ADM16
Caution: Federal law prohibits transfer of this drug to any person other than the patient for whom it was prescribed.
RX ONLY-KEEP OUT OF REACH OF CHILDREN
Dosage: See package insert. Store between 66-77 degrees F

M
NDC 61919-593-30
May cause drowsiness or dizziness. Alcohol may intensify this effect. Use Care when operating dangerous machinery. Medication should be taken with plenty of water.

CHLORDIAZEPOXIDE C-IV 25mg
NDC 61919-593-30 30 Caps
Lot Exp Date 11/20
Ntg NDC 43547-253-10

CHLORDIAZEPOXIDE C-IV 25mg
NDC 61919-593-30 30 Caps
Lot Exp Date 11/20
Ntg NDC 43547-253-10

CHLORDIAZEPOXIDE C-IV 25mg
NDC 61919-593-30 30 Caps
Lot Exp Date 11/20
Ntg NDC 43547-253-10

CHLORDIAZEPOXIDE C-IV 25mg
NDC 61919-593-30 30 Caps
Lot Exp Date 11/20
Ntg NDC 43547-253-10

Dir. By: Sotco Healthcare U.S., LLC
Cantbury, NJ 08812
NDC 43547-253-10

Mfg. Lot: 6170316

scumef
DPX.FRM.018

CHLORDIAZEPOXIDE

chlordiazepoxide capsule, gelatin coated

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:61919-593(NDC:43547-253)
Route of Administration	ORAL	DEA Schedule	CIV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CHLORDIAZEPOXIDE HYDROCHLORIDE (UNII: MFM6K1XWDK) (CHLORDIAZEPOXIDE - UNII:6RZ6XEZ3CR)	CHLORDIAZEPOXIDE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
TALC (UNII: 7SEV7J4R1U)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
GELATIN (UNII: 2G86QN327L)	
STARCH, CORN (UNII: O8232NY3SJ)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q815X)	

Product Characteristics

Color	green (GREEN AND WHITE)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	S253;S
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61919-593-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	04/04/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA085475	03/04/2016	

Labeler - DIRECT RX (079254320)**Establishment**

Name	Address	ID/FEI	Business Operations
DIRECT RX		079254320	repack(61919-593)

Revised: 4/2019

DIRECT RX