**LIBRAX®**
(chlordiazepoxide HCl
(c lidinium bromide)
CAPSULES

**DESCRIPTION**
Librax combines in a single capsule formulation the antianxiety action of chlordiazepoxide hydrochloride and the anticholinergic/ spasmylic effects of atidinium bromide. Each Librax capsule contains the active ingredients 5 mg chlordiazepoxide hydrochloride and 2.5 mg atidinium bromide. Each capsule also contains the inactive ingredients corn starch, lactose monohydrate, talc, methylparaben, propylparaben, potassium sorbate, D&C Yellow No. 10, FD&C Green No. 3, titanium dioxide, and gelatin. Chlordiazepoxide hydrochloride is a versatile, therapeutic agent of proven value for the relief of anxiety and tension. It is indicated in anxiety, tension or apprehension which are significant components of the clinical profile. It is among the safer of the effective psychopharmacologic compounds.

Chlordiazepoxide hydrochloride is 7-chloro-2-methylaminoo-5- phenyl-1H-1-benzazepine-4-oxide hydrochloride. A colorless, crystalline substance, it is soluble in water. It is unstable in solution and the powder must be protected from light. The molecular weight is 306.22. The structural formula of chlordiazepoxide hydrochloride is as follows:

![Structural formula of chlordiazepoxide hydrochloride](image)

Clidinium bromide is a synthetic anticholinergic agent which has been shown in experimental and clinical studies to have a pronounced antispasmodic and antisecretory effect on the gastrointestinal tract. Structurally clidinium bromide is:

![Structural formula of clidinium bromide](image)

**ANIMAL PHARMACOLOGY**
Chlordiazepoxide hydrochloride has been studied extensively in many species of animals and these studies are suggestive of action on the limbic system of the brain, which recent evidence indicates is involved in emotional responses. Hostile monkeys were made tame by oral drug doses, which did not cause sedation. Chlordiazepoxide hydrochloride revealed a “taming-action” with the elimination of fear and aggression”. The taming effect of clidinium bromide was further demonstrated in rats made violent by lesions in the septal area of the brain. The drug dosage which effectively blocked the violent reaction was well below the dose which caused sedation in these animals.

The oral LD₅₀ of single doses of chlordiazepoxide hydrochloride, calculated according to the method of Miller and Tainter, is 220 ± 51 mg/kg as determined in mice observed over a period of 5 days following dosing. Clidinium bromide is an effective anticholinergic agent with activity approximating that of atropine sulfate against acetylcholine-induced spasms in isolated intestinal strips. Oral administration in mice, if proved an effective antialogogue in preventing pilocarpine-induced salivation. Spontaneous intestinal motility in both rats and dogs is reduced following oral dosing with 0.1 to 0.25 mg/kg. Potent cholinergic ganglionic blocking effects (vagal) were produced with intravenous use in anesthetized dogs.

**Oral dosages of 2.5 mg/kg to dogs produced signs of nasal dryness and slight pupillary dilatation. In two other species, monkeys and rabbits, doses of 5 mg/kg, po, given three times daily for 5 days did not produce apparent secretory or visual changes. The oral LD₅₀ of single doses of clidinium bromide is 860 ± 57 mg/kg as determined in mice observed over a period of 5 days following dosing, the calculations were made according to the method of Miller and Tainter.

Effects on Reproduction
Reproduction studies in rats fed chlordiazepoxide hydrochloride, 10, 20 and 80 mg/kg daily, and bred through one or two matings showed no congenital anomalies, nor were there adverse effects on lactation of the dams or growth of the newborn. However, in another study at 100 mg/kg/day, there was a significant decrease in the life span of the offspring. A slight increase in the birth weight and a decreased in the body weight gain in the second generation were noted in mice treated with clidinium bromide. In the first matings, no significant differences were noted between the control or the treated groups, with the exception of a slight decrease in the number of animals surviving during lactation among those receiving the highest dosage. As with all anticholinergic drugs, an inhibitory effect on the offspring was noted. In the second matings, similar effects were observed but were noted for a slight decrease in the number of pregnant females and in the number of pigs surviving until weaning. No congenital anomalies were observed in both matings in either the control or treated groups. Additional animal reproduction studies are in progress.

**INDICATIONS AND USAGE**
Librax is indicated to control emotional and somatic factors in gastrointestinal disorders. Librax may also be used as adjunctive therapy in the treatment of peptic ulcer and in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis.

**CONTRAINDICATIONS**
Librax is contraindicated in the presence of glaucoma (since the anticholinergic component may produce some degree of mydriasis) and in patients with prostatic hypertrophy and benign neoplasms of the nose. Librax is contraindicated in patients who are known hypersensitivity to chlordiazepoxide hydrochloride and/or clidinium bromide.

**WARNINGS**
Concomitant use of benzodiazepines, including Librax, and opioids may result in profound sedation, respiratory depression, coma, and death. Because of these risks, reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. Observational studies have demonstrated that concomitant use of opioid analgesics and benzodiazepines increases the risk of drug-related mortality compared to use of opioids alone. If a decision is made to prescribe Librax concomitantly with opioids, prescribe the lowest effective dosage and minimum duration of concomitant use. Take a patient history for symptoms of drug addiction. Your healthcare provider can tell you more about the differences between physical dependence and drug addiction.

**What is Librax?**
Librax is a prescription medicine that is used with other therapies for the treatment of:
- stomach (peptic) ulcers
- irritable bowel syndrome (IBS)
- inflammation of the colon called acute enterocolitis
- contains the medicines chlordiazepoxide HCl and clidinium bromide
- can be abused or lead to dependence. Keep Librax in a safe place to prevent misuse and abuse. Selling or giving away Librax 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 Librax is safe and effective in children.
How should I take Librax?

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

What are the possible side effects of Librax? Librax may cause serious side effects, including: See “What is the most important information I should know about Librax?”

The most common side effects of Librax include:
- dry mouth
- nausea
- skin problems
- blurred vision
- constipation
- 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 Librax.

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 Librax?
- Store Librax at room temperature 77°F (25°C).
- Keep Librax and all medicines out of the reach of children.

General information about the safe and effective use of Librax.

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

What are the ingredients in Librax?

Active ingredient: chlordiazepoxide hydrochloride and clidinium bromide

Inactive ingredients: corn starch, lactose, and talc. Gelatin capsule shells may contain:
- methylparaben, propylparaben, and potassium sorbate, with the following dye systems: D&C Yellow No. 10 and FD&C Green No. 3.

Manufactured for:
Valeant Pharmaceuticals North America LLC
Bridgewater, NJ 08807 USA

Manufactured by:
Valeant Pharmaceuticals International, Inc.
Steinbach, MB R5G 127 Canada

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Usage in Pregnancy

An increased risk of congenital malformations associated with the use of minor tranquilizers (chlordiazepoxide, diazepam and meprobamate) during the first trimester of pregnancy has been suggested in several studies. Because use of these drugs is rarely a matter of urgency, their use during this period should almost always be avoided. The possibility that a woman of childbearing potential may be pregnant at the time of institution of therapy should be considered before treatment is initiated. It should be understood that if she becomes pregnant during therapy or intent to become pregnant they should communicate with their physicians about the desirability of discontinuing the drug.

As with all anticholinergic drugs, an inhibiting effect on lactation may occur (see ANIMAL PHARMACOLOGY).

OVERDOSAGE

Manifestations of chlordiazepoxide hydrochloride overdose include somnolence, ataxia, and respiratory depression. Respiration, pulse and blood pressure should be monitored, as in all cases of drug overdosage. Ataxia, if present, in general, these effects have not been minimal following chlordiazepoxide hydrochloride overdose.

While the signs and Symptoms of Librax overdose may be produced by either of its components, usually such symptoms will be overshadowed by the anticholinergic actions of clidinium bromide. The symptoms of clidinium bromide are excessive dryness of mouth, blurring of vision, urinary hesitancy and constipation.

General supportive measures should be employed, along with immediate gastric lavage. Administer physostigmine 0.5 to 2 mg at a rate of no more than 1 mg/min. This may be repeated in 1 to 4 mg doses if arrhythmias, convulsions or deep coma recur. Intravenous fluids should be administered and an adequate airway maintained. Hypotension can be combated by the use of levaterenol or metaraminol. Methylphenidate or caffeine and sodium benzoate may be given to combat CNS-depressive effects. Dialysis is of limited value. Should excitation occur, barbiturates should not be used. As with the management of intentional overdosage with any drug, it should be borne in mind that multiple agents may have been ingested.

Withdrawal symptoms of the barbiturate type have occurred after the discontinuation of benzodiazepines (see DRUG ABUSE AND DEPENDENCE).

PRECAUTIONS

In debilitated patients, it is recommended that the dosage be limited to the smallest effective amount to preclude the development of ataxia, overstimulation or confusion (not more than 2 Librax capsules per day). Dosage should be increased gradually as needed and tolerated.

In general, the concomitant administration of Librax and other psychotropic agents is not recommended. If such combination therapy seems indicated, close consideration should be given to the pharmacology of the agents to be employed—particularly when withdrawal symptoms, similar in character to those noted with barbiturates and alcohol (convulsions, tremor, abdominal and muscle cramps, vomiting and sweating), have occurred following abrupt discontinuation of chloropropamide. The more severe withdrawal symptoms usually have been limited to those patients who had received excessive doses over an extended period of time. Generally milder withdrawal symptoms (e.g., tremor, diaphoresis and insomnia) have been reported following abrupt discontinuation of benzodiazepines taken continuously at therapeutic levels for several months. Consequently, after extended therapy, abrupt discontinuation should generally be avoided. If a gradual dosage tapering schedule followed. Addiction-prone individuals (such as drug addicts or alcoholics) should be treated with caution when receiving chloropropamide or other psychotropic agents because of the predisposition of such patients to habilization and dependence.

DOSAGE AND ADMINISTRATION

Because of the varied individual responses to tranquilizers and anticholinergics, the optimum dosage of Librax varies with the diagnosis and response of the individual patient. The dosage therefore, should be individualized for maximum beneficial effects. The usual maintenance dose is 1 or 2 capsules, 3 or 4 times a day administered before meals and at bedtime.

Geriatric Dosing

Dose should be limited to the smallest effective amount to preclude the development of ataxia, overstimulation or confusion. The initial dose should not exceed 2 Librax capsules per day, to be increased gradually as needed and tolerated.

HOW SUPPLIED

Librax is available in light green opaque capsules, each containing 5 mg chlordiazepoxide hydrochloride and 2.5 mg clidinium bromide in bottles of 150 (NDC 0187-4100-10), with LIBRAX® ICN imprinted on the body of the capsule.

Stain at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F).

Keep out of reach of children.

Dispense in a light, tight-resistant container as defined in USP/NF.

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