

PRESCRIBING INFORMATION

CHLORAX Capsules

(Chlordiazepoxide HCl ó Clidinium Bromide)
5 -2.5 mg

Anticholinergic - Anxiolytic

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(Chlordiazepoxide HCl ó Clidinium Bromide)

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Pharmacology:

Chlordiazepoxide is a benzodiazepine CNS depressant with anxiolytic and sedative properties.

Although the mechanism of action for the behavioral and neurophysiological effects of benzodiazepines has not been defined, it is postulated that they exert their antianxiety effect by selective inhibition of electrical discharge from the limbic system without depression of the rest of the brain or autonomic nervous system.

Clidinium bromide is a synthetic quaternary ammonium agent with anticholinergic and antispasmodic activity. It inhibits gastrointestinal motility and diminishes gastric acid secretion. The drug's anticholinergic activity approximates that of atropine sulfate and propantheline bromide.

Indications:

As adjunctive therapy in the treatment of peptic ulcer and in the treatment of the irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis, when these are associated with excessive anxiety and tension.

Contraindications:

Glaucoma (clidinium bromide may produce some degree of mydriasis); prostatic hypertrophy and benign bladder neck obstruction; psychotic patients; hypersensitivity to any of the components.

Precautions and Adverse Effects:

For Chlordiazepoxide, see chlordiazepoxide prescribing information.

In addition, clidinium bromide may produce dryness of mouth, blurring of vision, urinary hesitancy and constipation. Constipation may occur when chlordiazepoxide plus clidinium therapy is combined with other spasmolytics and/or a low residue diet.

Anticholinergic drugs may exert an inhibiting effect on lactation.

In the presence of high environmental temperature, heat prostration may occur with the use of anticholinergics due to decreased sweating.

Overdose:

Symptoms: Manifestations of chlordiazepoxide overdose include somnolence, confusion, coma and diminished reflexes.

The symptoms of clidinium bromide overdose progress from an intensification of the usual side effects (see Adverse Effects) to CNS disturbances ranging from restlessness and excitement to psychotic behavior, circulatory changes (flushing, tachycardia, fall in blood pressure), respiratory failure, paralysis and coma.

Treatment: Employ general supportive measures, along with immediate gastric lavage. Monitor respiration, pulse and blood pressure. Administer physostigmine 0.5 to 2 mg at a rate of no more than 1 mg/minute. This may be repeated in 1 to 4 mg doses if arrhythmias, convulsions or deep coma recur. Administer i.v. fluids and maintain an adequate airway. Cardiovascular and CNS stimulants may be used if necessary. Dialysis is of limited value. Should excitation occur, do not administer barbiturates.

Dosage:

Should be individualized for maximum beneficial effects because of the varied individual responses to benzodiazepines and anticholinergics. The optimum dosage will vary with the diagnosis and response of the individual patient.

The usual adult maintenance dose is 1 to 2 capsules 3 or 4 times/day, administered before

meals and at bedtime. In the elderly, limit the dosage to the smallest effective amount to preclude the development of adverse reactions. No more than 2 capsules per day should be administered initially and increased gradually as needed and tolerated.

Supplied:

Each green No. 4 capsule contains chlordiazepoxide HCl 5 mg and clidinium bromide 2.5 mg.

Bottles of 100, 500 and 1000.