

Librax[®]

(Clidinium and Chlordiazepoxide)

Pharmacologic Category: Antispasmodic Agent, Gastrointestinal; Benzodiazepine

Available Products/Cost: Capsules (Chlordiazepoxide HCl 5 mg & Clidinium Bromide 2.5 mg):

Generic: \$29.99 (30 capsules)

Brand name: \$331.18 (60 capsules)

(www.drugstore.com)

Pharmacology

Chlordiazepoxide: CNS depressant/BZD – Relieves anxiety

Clidinium: Anticholinergic – Improves symptoms of cramping and abdominal/stomach pain by decreasing stomach acid and by slowing the intestines

Indications

- 1) Adjunct treatment of peptic ulcer
- 2) Treatment of irritable bowel syndrome (IBS)

Dosing/Administration

- Peptic Ulcer adjunct or Treatment of IBS: 1-2 capsules po 3-4 times daily
- This medication should be taken before meals and at bedtime
- Do not discontinue abruptly. (Taper dose gradually).

Adverse Effects (1% to 10%)

- Drowsiness
- Ataxia
- Confusion
- Anticholinergic side effects
- Dry mouth
- Constipation
- Nausea

<1%: Agranulocytosis, blood dyscrasias, extrapyramidal symptoms, hepatic dysfunction, jaundice, syncope

Contraindications

- Hypersensitivity to clidinium, chlordiazepoxide, or any component of the formulation
- Glaucoma
- Prostatic hyperplasia
- Benign bladder neck obstruction
- Pregnancy

Warnings/Precautions

- Benzodiazepines have been associated with anterograde amnesia.
- May cause CNS depression (Caution patients about mental alertness)
- Paradoxical reactions have been reported in adolescent/pediatric or psychiatric patients.
- Use caution in patients with depression, particularly if suicidal risk may be present.

- Use with caution in patients with a history of drug abuse or acute alcoholism; (potential for drug dependency)
- Use with caution in patients with hepatic impairment, renal impairment, an impaired gag reflex or respiratory disease
- May potentiate effects of ethanol or other sedative drugs
- Does not have analgesic, antidepressant, or antipsychotic properties.
- Rebound or withdrawal symptoms may occur following abrupt discontinuation

Drug Interactions

Librax® may increase the levels/effects of: Alcohol, Anticholinergics, Cannabinoids, Clozapine, CNS depressants, Methotrimeprazine, Phenytoin, Potassium chloride

Levels/Effects of Librax® may be increased by: Antifungal agents, Aprepitant, Calcium channel blockers, Cimetidine, CYP3A4 inhibitors, Dasatinib, Disulfiram, Fluconazole, Fosaprepitant, Grapefruit juice, Isoniazid, Macrolide antibiotics, MAO inhibitors, Methotrimeprazine, Nefazodone, Oral contraceptive (Estrogens & Progestins), Pramlintide, Protease inhibitors, PPIs, SSRIs.

Librax® may decrease the levels/effects of: Acetylcholinesterase inhibitors, Secretin

Levels/Effects of Librax® may be increased by: Acetylcholinesterase inhibitors, Carbamazepine, CYP3A4 inducers, Deferasirox, Rifamycin derivatives, St Johns Wort, Theophylline derivatives, Yohimbine

Special Populations

Elderly: Avoid use in elderly patients due to anticholinergic adverse effects and uncertain effectiveness. Benzodiazepines with long half-lives may cause prolonged sedation and increase the risk of falls and fracture. (Short- or intermediate-acting benzodiazepines are preferred in elderly patients).

Pediatrics: Safety and effectiveness has not been established.

Pregnancy: Risk Factor "D". Use in 1st trimester increases risk for congenital malformations and should be avoided during this period.

Lactation: Contraindicated (enters breast milk)

Pharmacokinetics - Half-life: 5-30 hours (Chlordiazepoxide)