100 mm

215 mm

Librax®

Chlordiazepoxide 5 mg +
Clidinium bromide 2.5 mg

As adjunctive therapy in the treatment of peptic ulcer and irritable bowel syndrome.

Composition
Each dragee contains: 5 mg Chlordiazepoxide (7-Chloro-2methylamino-5-phenyl-3H-1, 4benzodiazepine-4-oxide) and 2.5 mg Clidinium bromide (3-Benziloyloxy-1-methylquinuclidinium bromide). 1 dragee contains 279 mg carbohydrate (4.6 kJ).

Mode of Action
Chlordiazepoxide has antianxiety, sedative, appetite stimulating and weak analgesic actions. The precise mechanism of action is not known. The drug blocks EEG arousal from stimulation of the brain stem reticular formation. It takes several hours for peak blood levels to be reached and the half -life of the drug is between 24 and 48 hours. After the drug is discontinued plasma levels decline slowly over a period of several days. Chlordiazepoxide is excreted in the urine with 1% to 2% unchanged and 3% to 6% as a conjugate. Clidinium (other synthetic quaternary ammonium compounds), is ionized and rarely affect the central nervous system because they do not readily cross the blood-brain barrier. Their ionization is largely responsible for the wide individual variability in absorption noted after oral administration. Most of their actions are attributable to the antimuscarinic effect of usual therapeutic doses. Some antispasmodic actions of quaternary ammonium compounds may be due to their relatively specific ganglionic blocking effects in the gastrointestinal tract.

Indications
As adjunctive therapy in the treatment of peptic ulcer and irritable bowel syndrome.

Dosage
Usual adult dose:
Oral, 1 or 2 dragees one to four times a day, thirty to sixty minutes before meals or food, the dosage then being adjusted as needed and tolerated.

Usual geriatric dose:
Oral, initially no more than 1 dragee two times a day, the dosage then being adjusted as needed and tolerated.
Usual pediatric dose:
Dosage has not been established.

Contraindications
Librax is contraindicated for patients with known hypersensitivity to chlordiazepoxide or clidinium bromide, and also in the presence of glaucoma. Patients with reflux esophagitis because Librax decrease both esophageal and gastric motility and relax the lower esophageal sphincter.

Warnings and Precautions
Particular caution is advised in patients with prostatic hypertrophy or myasthenia gravis. Depending on dosage, administration and individual susceptibility, Librax may modify the patient's reaction (e.g. driving ability, behavior in traffic). Blood, renal and hepatic function tests are recommended if treatment is given for prolonged periods.

Dependence
The use of benzodiazepines and benzodiazepine-like agents may lead to the development of physical and psychic dependence. The risk of dependence increases with dose and duration of treatment; it is also greater in patients with a history of alcohol or drug abuse. Once physical dependence has developed, abrupt termination of treatment will be accompanied by withdrawal symptoms. These may consists of headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability. In severe cases, the following symptoms may occur: derealization, depersonalization, hyperacusis, numbness and tingling of the extremities, hypersensitivity to light, noise and physical contact, hallucinations or epileptic seizures.

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Since the risk of withdrawal phenomena and rebound phenomena is greater after abrupt discontinuation of treatment, it is recommended that the dosage be decreased gradually.

Pregnancy, Nursing Mothers
For fundamental medical reasons, Librax should not be administered in early pregnancy unless it is considered imperative to do so. Chlordiazepoxide and Clidinium bromide pass into the milk of nursing mothers.

Over dosage
Measures recommended for accidental or deliberate over dosage are gastric lavage, maintenance of airway patency and surveillance of the patient. If symptoms attributable to chlordiazepoxide predominate, flumazenil is indicated. The usual precautions in treating patients with impaired renal or hepatic function should be observed. To assure the safe and effective use of benzodiazepines, patients should be informed that since Librax may produce psychological and physical dependence it is advisable that they consult with their physician before either increasing the dose or abruptly discontinuing this drug. Since antacids may interfere with absorption of anticholinergic agents, these drugs should not be given concomitantly, at interval of at least one hours is suggested.

Side Effects
* Side effects such as dryness of the mouth, constipation and disorders of micturition may occasionally occur. In elderly patients slight drowsiness may sometimes be observed, especially at the beginning of treatment. This usually disappears spontaneously or in response to a dosage reduction.
* Agranulocytosis, granulocytopenia or leucopenia, allergic reactions. In a few instances syncope has been reported.
* Other adverse reaction reported during therapy include isolated instances of skin eruptions, edema, minor menstrual irregularities, nausea, constipation, extra pyramidal symptoms, as well as increased and decreased libido. Such side effects have been infrequent and are generally controlled with reduction of dosage.

Interactions
If Librax is taken concurrently with preparations containing anticholinergic ingredients, e.g. amantadine, various antihistamines, butyrophenones, phenotiazines, tricyclic and tetracyclic antidepressants, the anticholinergic action of clidinium bromide is potentiated. During treatment with Librax, patients should avoid alcohol since the individual response can not be foreseen.

Stability
This medicine should not be used after the expiry date shown on the pack.

Packaging
Box, 10 strips of 10 dragees Reg. No.

Store at below 30°C.
Keep all medicine out of the reach of children

On medical prescription only
Harus dengan resep dokter

Manufactured by:
PT. COMBIPHAR, Bandung-Indonesia
For :
PT. MUGI LABORATORIES, Bekasi-Indonesia

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