PHARMALINE

Lexane

Anxiolytic

DESCRIPTION

Lexane, brand of Bromazepam, is a benzodiazepine antianxiety agent.

ACTIONS

The actions of ***Lexane*** are mediated by enhancement of the activiy of gamma-aminobutyric acid (GABA), a major inhibitory neurotransmitter at all levels of the neuroaxis, including the spinal cord, hypothalamus, hippocampus, substantia nigra, cerebellar cortex, and cerebral cortex. *Lexane* appears to increase the efficiency of GABA-ergic synaptic inhibition by acting on specific receptors, which leads to a decrease in the firing rate of critical neurons. ***Lexane*** does not substitute GABA but requires the presence of the neurotransmitter to elicit a response. In low dosage, ***Lexane*** selectively reduces tension and anxiety. In high dosage, sedative and muscle-relaxant properties appear.

PHARMACOKINETICS

Peak plasma concentrations are reached within one to two hours after oral administration of bromazepam. Plasma protein binding of bromazepam is 70%. Half-life elimination of bromazepam is 10 - 20 hours. Bromazepam is metabolized in the liver, and the metabolites are excreted in the urine mainly in conjugated form.

INDICATIONS

* Emotional disturbances: anxiety and tension states, anxious depressive mood, nervous tension, agitation and insomnia.
* Anxiety and tension related to functional disturbances:
- Of the cardiovascular and the respiratory systems: pseudoangina pectoris, anxiety tachycardia, emotiogenic hypertension, dyspnea and hyperventilation;
- Of the gastrointestinal tract: irritable bowel syndrome, ulcerative colitis, epigastric pain, spasm, bloating and diarrhea;
- Of the genitourinary tract: irritable bladder, urinary frequency and dysmenorrhea.
- Other psychosomatic disturbances: psychogenic headache and psychogenic dermatosis.

Lexane is also suitable for treatment of anxiety and tension states originating from chronic organic disease and as an adjuvant to psychotherapy in psychoneurosis.

CONTRAINDICATIONS

Lexane must not be administered to patients with known hypersensitivity to benzodiazepines.

PRECAUTIONS

In patients with myasthenia gravis care should be taken with use of ***Lexane***.
As Bromazepam can pass into the breast milk, nursing mothers must not take ***Lexane***.
In the first six hours after taking high doses, patients should avoid driving a car or operating dangerous machinery because ***Lexane*** may modify the patient's reactions.

DRUG INTERACTIONS

If *Lexane* is combined to alcohol and other centrally active drugs such as neuroleptics, tranquilizers, antidepressants, hypnotics, analgesics and anesthetics, its central-sedative effect may be enhanced.

ADVERSE REACTIONS

Fatigue, drowsiness and rarely muscle weakness may occur with high doses. These symptoms regress on reduction of the dosage.
During long term treatment with high doses, as with all hypnotic, sedative and tranquilizing preparations, dependence may develop in predisposed individuals.
Treatment with ***Lexane*** should be terminated if reactions such as acute anxiety, hallucinations, insomnia or excitation occur.

DOSAGE & ADMINISTRATION

Mild to moderate cases: 1,5 - 3 mg up to three times daily.
Severe cases: 6 - 12 mg two or three times daily.
Treatment should begin with low doses, gradually increasing to the optimum level, and withdrawal should be gradual when long treatment is given.
In children, the dosage should be adjusted to their body weight.
Elderly and debilitated patients require lower doses.

AVAILABILITY

Tablets

- Packs of 30 tablets each containing Bromazepam 1,5 mg, Excipient q.s. 1 tablet.
Reg Lebanon 0236896
- Packs of 30 tablets each containing Bromazepam 3 mg, Excipient q.s. 1 tablet.
Reg Lebanon 0236897
- Packs of 30 tablets each containing Bromazepam 6 mg, Excipient q.s. 1 tablet.
Reg Lebanon 0236899
- Packs of 1000 tablets each containing Bromazepam 3 mg, Excipient q.s. 1 tablet.
Reg Lebanon 0236898

* Lexane is a Trade Mark.