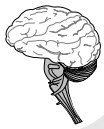

Laxyl®

Bromazepam

Tranquillizer

COMPOSITION

Laxyl® tablet : Each tablet contains Bromazepam BP 3 mg.

PHARMACOLOGY

Laxyl® (Bromazepam) is a benzodiazepine with anxiolytic and sedative properties which are of value in the symptomatic relief of pathological anxiety. Bromazepam is rapidly absorbed from the gastro-intestinal tract. Peak plasma concentrations are usually reached within two hours of oral administration of bromazepam. Steady state plasma concentrations are reached in around five to nine days. Bromazepam is metabolized in liver. Quantitatively, two metabolites predominate: 3-hydroxy-bromazepam and 2-(2-amino-5-bromo-3-hydroxybenzoyl) pyridine. Metabolites of Laxyl® (Bromazepam) do not contribute significantly to the effects of the drug.

INDICATION

Laxyl® is indicated for the treatment of anxiety & anxiety related to disorders like,

Emotional disturbance: Acute tension and anxiety states. Difficulties in interpersonal contact. Agitation, insomnia, anxious and agitated depressive reactions.

Functional disturbance in the cardiovascular and respiratory systems: Pseudoangina pectoris, precordial anxiety, tachycardia, emotiogenic hypertension, dyspnea and hyperventilation.

Functional disturbance in the gastrointestinal system: Irritable bowel syndrome, epigastric pain, spasm, bloting diarrhoea, etc.

Functional disturbance in the genitourinary system: Frequency, Irritable bladder, and dysmenorrhea.

Psychosomatic disorders: Psychogenic headache, psychogenic dermatosis, asthma, gastric & duodenal ulcer, and ulcerative colitis. Emotional reactions to chronic organic disease. Adjuvant to psychotherapy in psychoneurosis.

DOSAGE AND ADMINISTRATION

The optimum dosage and frequency of administration of Bromazepam should be based on the individual patient, the severity of symptoms and previous psychotropic drug history. The usual dosage in general practice is from 3 mg to 18 mg daily in divided doses. In exceptional circumstances, in

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hospitalized patients, up to the maximum daily dosage of 60 mg, in divided doses, may be given.

Use in elderly: Elderly patients are more sensitive to the actions of Bromazepam. Doses should not exceed half of those normally recommended. The lowest dose which can control symptoms should be used. Treatment should not be continued at the full dose beyond four weeks. Long-term chronic use is not recommended. Treatment should always be tapered off gradually. Patients who have taken

benzodiazepines for a prolonged time may require a longer period during which doses are reduced. Specialist help may be appropriate.

Use in Children: Bromazepam is not recommended for paediatric use.

Bromazepam tablets are for oral administration.

CONTRAINDICATION

Patients with known sensitivity to benzodiazepines; acute pulmonary insufficiency; respiratory depression; phobic or obsessional states; chronic psychosis,

PRECAUTIONS AND WARNING

In patients with chronic pulmonary insufficiency, and in patients with chronic renal or hepatic disease, dosage may need to be reduced. Amnesia may occur. In cases of loss or bereavement, psychological adjustment may be inhibited by benzodiazepines. If Bromazepam is combined with centrally-acting drugs such as neuroleptics, tranquillisers, antidepressants, hypnotics, analgesics and anaesthetics, the sedative effects are likely to be intensified. The elderly require special supervision. Patients should be advised that, like all medicaments of this type, Bromazepam may modify patients performance at skilled tasks (driving, operating machinery, etc.) to a varying degree depending upon dosage, administration and individual susceptibility. Patients should further be advised that alcohol may intensify any impairment and should therefore be avoided during treatment. The dependence potential of the benzodiazepines is low, particularly when limited to short-term use, but this increases when high doses are used, especially when given over long periods. This is particularly so in patients with a history of alcoholism or drug abuse or in patients with marked personality disorders. Regular monitoring in such patients is essential, routine repeat prescriptions should be avoided and treatment should be withdrawn gradually. Symptoms

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such as depression, nervousness, rebound insomnia, irritability, sweating, and diarrhoea have been reported following abrupt cessation of treatment in patients receiving even normal therapeutic doses for short periods of time. In rare instances, withdrawal following excessive dosages may produce confusional states, psychotic manifestations and convulsions. Abnormal psychological reactions to benzodiazepines have been reported. Rare behavioural effects include paradoxical aggressive outbursts, excitement, confusion, and the uncovering of depression with suicidal tendencies. Extreme caution should therefore be used in prescribing benzodiazepines to patients with personality disorders. When Bromazepam is used in conjunction with antiepileptic drugs, side-effects and toxicity may be more evident, particularly with hydantoins or barbiturates or combinations including them. This requires extra care in adjusting dosage in the initial stages of treatment. Known inhibitors of hepatic enzymes, e.g. cimetidine, have been shown to reduce the clearance of benzodiazepines and may potentiate their action and known inducers of hepatic enzymes, e.g. rifampicin, may increase the clearance of benzodiazepines.

SIDE EFFECT

Common adverse effects include drowsiness, sedation, unsteadiness and ataxia; these are dose-related and may persist into the following day, even after a single dose. Drowsiness may be a particular problem when Bromazepam is used in higher dosage in some patients, especially if they are unused to this form of therapy. The elderly are particularly sensitive to the effects of centrally depressant drugs and may experience confusion; especially if organic brain changes are present; the dosage of Bromazepam should not exceed one-half that recommended for other adults. Other adverse effects are rare and include headache, vertigo, hypotension, gastro-intastinal upsets, skin rashes, visual disturbances, changes in libido, and urinary retention. Isolated cases of blood dyscrasias and jaundice have also been reported.

USE IN PREGNANCY AND LACTATION

There is no evidence as to drug safety in human pregnancy, nor is there evidence from animal work that it is free from hazard. Do not use during pregnancy, especially during the first and last trimesters, unless there are compelling reasons. The administration of high doses or prolonged

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administration of low doses of benzodiazepines in the last trimester of pregnancy has been reported to produce irregularities in the foetal heart rate, and hypotonia, poor sucking and hypothermia in the neonate. Benzodiazepines have been detected in breast milk. If possible, the use of Bromazepam should be avoided during lactation.

STORAGE CONDITION

Bromazepam tablets should be stored in cool and dry place, protected from light & moisture.

HOW SUPPLIED

Laxyl® Tablet : 5 x 10 tablets in blister packing.

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