

### Composition

**Laxyi**® tablet: Each tablet contains Bromazepam BP 3 mg.

Pharmacology

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.

#### Indication

- Emotional disturbance: Acute tension and anxiety states.
  Agitation, insomnia, anxiety and age related depressive reactions.
- Functional disturbance in the cardiovascular respiratory system: Pseudoangina pectoris, precordial anxiety, tachycardia, emotiogenic hypertension, dyspnea and hyperventilation.
- In the gastrointestinal system: Irritable bowel syndrome, epigastric pain, spasm, bloting diarrhoea, etc.
- In the genitourinary system: Irritable bladder and dysmenorrhea.
- psychosomatic disorders: Psychogenic headache, psychogenic dermatosis, asthma, gastric and duodenal ulcer, ulcerative colitis. Emotional reactions to chronic oraganic diseases.

### **Dosage & 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 hospitalised 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.

Use in Children: Bromazepam is not recommended for paediatric use. Bromazepam tablets are for oral administration.

### Contraindication

Patients with known hypersensitivity 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. If Bromazepam is combined with centrally acting drugs such as alcohol, 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).

#### Side Effect

Common side 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.

Other side effects are rare and include headache, vertigo, hypotension, gastro-intestinal upsets, skin rashes, visual disturbance & change in libido.

# **Use in Pregnancy and Lactation**

Use of benzodiazepines should be avoided during pregnancy, fetus may be affected.

Bromazepam is secreted through human milk. So nursing mothers should not use this drug.

### Overdose

Signs may include drowsiness, ataxia and dysarthria, with coma in severe cases.

## Storage

Protect from light and moisture, store below  $30^{\circ}$  C. Keep out of reach of children.

## **How Supplied**

**Laxyl®** tablet: Each box contains 50 tablets in blister pack.

Manufactured by

