

Restol[®]

Bromazepam Tablet

DESCRIPTION

Restol[®] is a preparation of Bromazepam. Bromazepam selectively reduces anxiety, tension and nervousness. In high dosage, sedative and muscle-relaxant properties appear.

INDICATIONS

Emotional disturbances: Anxiety and tension states, as adjuvant therapy for the anxiety in depressed patients, nervous tension, restlessness, anxiety and tension-related insomnia.

Cardiovascular and respiratory systems: Pseudoangina pectoris, pericardial anxiety, tachycardia, emotiogenic hypertension, dyspnea and hyperventilation.

Gastrointestinal tract: Irritable bowel syndrome, ulcerative colitis, epigastric pain, spasm, meteorism and diarrhea.

Urogenital tract: Irritable bladder, urinary frequency, dysmenorrhea.

Other psychosomatic disturbances: Psychogenic headache, psychogenic dermatoses.

DOSAGE AND ADMINISTRATION

Adults: 3-18 mg daily in divided doses. In exceptional circumstances, in case of hospitalized patients, maximum daily dosage of 60 mg, in divided doses, may be given.

Elderly or debilitated: Half of the adult dose.

Children: Not recommended.

CONTRAINDICATIONS

Bromazepam is contraindicated in-patients with known hypersensitivity to benzodiazepines, acute pulmonary insufficiency, sleep apnea syndrome, myasthenia gravis, severe hepatic impairment, chronic psychosis.

PRECAUTIONS

Relative restrictions on use: Caution is required in-patients with chronic respiratory depression, as they are at risk of respiratory failure.

Alertness, reactive capacity: Sedation, amnesia and impairment of muscle function can impair the ability to drive a motor vehicle or operate machines.

SIDE-EFFECTS

Common side-effects include drowsiness, confusion, ataxia, amnesia and muscle weakness; these are dose related and may persist into the following day, even after a single dose. Other side effects are rare and include headache, vertigo, hypotension, salivation changes, gastro-intestinal disturbances, visual disturbances, dysarthria, blood disorders, jaundice, changes in libido and urinary retention.

USE IN PREGNANCY AND LACTATION

The safety of bromazepam in pregnant women has not been established. So, it should not be taken during pregnancy unless there is a compelling indication for its use and no safer therapeutic alternative is available. As Bromazepam is excreted in breast milk, use should be avoided during lactation.

PHARMACEUTICAL PRECAUTION

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Restol[®] Tablet: Box containing 3 strips of 10 tablets each. Each tablet contains Bromazepam BP 3 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

MIRPUR, DHAKA, BANGLADESH

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