

**PRESENTATION:**

Norry® 3mg tablet – Each tablet contains Bromazepam 3mg

DESCRIPTION:

Bromazepam belongs to a group of medicines called Benzodiazepines. It acts on receptors in the brain (GABA receptors) causing the release of a chemical called GABA (gamma amino butyric acid). GABA is a major inhibitory chemical in the brain involved in inducing sleepiness and control of anxiety. Bromazepam acts by increasing the activity of GABA, thereby reducing the functioning of certain areas of the brain. This results in sleepiness, a decrease in anxiety and relaxation of the muscles. In low doses, Bromazepam selectivity reduces tension and anxiety. In high doses, 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, emotionally conditioned 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 : The optimum dosage and frequency of administration of bromazepam should be based on individual patient, the severity of symptoms and previous psychotic drug history. The usual dosage in general practice is from 3mg to 18mg daily in divided doses. In exceptional circumstances, in hospitalized patients, up to the maximum daily dosage of 60mg, in divided doses is given.

Elderly patients: Elderly patients & those with impaired hepatic function may require lower doses.

Children : Not recommended.

CONTRAINDICATIONS:

Bromazepam should not be used in patients with known hypersensitivity to benzodiazepines or any other ingredients of this product, myasthenia gravis, chronic obstructive airways disease with incipient respiratory failure, severe hepatic insufficiency or sleep apnoea syndrome.

SIDE EFFECTS:

The possible side effects are headache, confusion, addiction to the medicine (dependence), muscle weakness, loss of memory (amnesia), drowsiness and light headedness the next day, shaky movements and unsteady walk (ataxia), unexpected increase in aggression (paradoxical

aggression), nausea, vomiting, fatigue, numbed emotion & reduced alertness. Blurred vision, seizure, dry mouth, rash, pruritus also have been reported rarely.

PRECAUTIONS:

Patients with known dependence on alcohol or drugs should not take benzodiazepines under medical supervision. Following the prolonged use of Bromazepam at therapeutic doses, withdrawal from the medication should be gradual.

In general, benzodiazepines should be prescribed for short periods only (e.g. 2-4 weeks). Patients with impaired renal and hepatic function should use benzodiazepines with caution and dosage reduction may be advised. Bromazepam is not recommended as primary therapy in patients with depression and/or psychoses. Caution must be exercised in administering Bromazepam to individuals known to be addiction prone. The use of benzodiazepines may lead to dependence, as defined by the presence of a withdrawal syndrome on discontinuation of the drug. Patients are warned not to operate dangerous machinery or motor vehicles.

DRUG-INTRACCTIONS:

When bromazepam co-administered with other medications which themselves produce CNS depression, e.g. barbiturates, alcohol, sedatives, antidepressants, hypnotics, anxiolytics, phenothiazines and antipsychotics, skeletal muscle relaxants, antihistamines, narcotic analgesics and anesthetics, produce additive CNS depressant effects. Caution should be taken in patients requiring drugs that inhibit the P450 enzymes (e.g. azole antifungals, macrolid antibiotics, HIV protease inhibitors, calcium channel blocking agents) as Bromazepam undergoes hepatic microsomal oxidation via the cytochrome P450 liver enzymes. Interactions have been reported between some benzodiazepines and anticonvulsants.

PREGNANCY AND LACTATION:

Bromazepam is a Pregnancy category 'C' drug. Benzodiazepines cross the placenta and may cause hypotonia, reduced respiratory function and hypothermia in the newborn infant. Continuous treatment during pregnancy and administration of high-doses in connection with delivery should be avoided.

As benzodiazepines pass into breast milk, breastfeeding mothers should not take Bromazepam.

STORAGE CONDITION:

Store in a cool and dry place, protected from light.

HOW SUPPLIED:

Norry® 3mg tablet-Each box contains 5X10's tablets in Alu-PVC blister strips.



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