

Only for the use of medical professionals

Zepam[®]

Bromazepam

Description

Bromazepam is an anti-anxiety treatment and a sedative. Bromazepam is in the group of drugs known as benzodiazepines, a class of antidepressants, anti-panic agents, and muscle relaxants. Bromazepam is usually used as a short term treatment for major anxiety, but is not recommended for use to relieve everyday stress or anxiety. This medication may also be used to relieve temporary insomnia, but if used daily, it will become ineffective in a few weeks.

Indication

1. Emotional disturbances: Acute tension and anxiety states, Difficulties in interpersonal contact, Agitation, Insomnia, anxious and agitated depressive reactions.
2. Functional disturbances in the cardiovascular and respiratory systems: Pseudoangina pectoris, Precordial anxiety, tachycardia, emotiogenic hypertension, dyspnea and hyperventilation.
3. In the gastrointestinal systems: Irritable bowel syndrome, epigastric pain, spasm, bloating, diarrhoea
4. In the genitourinary system: Irritable bladder and dysmenorrhoea.
5. Psychosomatic disorder: Psychogenic headache, psychogenic dermatosis, asthma, gastric and duodenal ulcer, ulcerative colitis.
6. Emotional reactions due to chronic organic diseases
7. Adjuvant to psychotherapy in psychoneurosis

Dosage and administration

Average dosing for outpatient therapy: 1.5-3mg up to three times daily. Severe cases, especially in hospitals: 6-12mg two or three times daily. Treatment of outpatients should begin with low doses, gradually increasing to as short as possible. The overall treatment generally should not be more than 8-12 weeks, including a tapering-off process.

Special dosage instructions:

Zepam[®] is usually not indicated in children, but if the physician feels Zepam[®] treatment is appropriate, then dose should be adjusted to their low body weight (about 0.1-0.3mg/kg). Elderly patient and those with impaired hepatic function require lower doses because of individual variations in sensitivity and pharmacokinetic.

Side-effects

The following undesirable effects may occur: Fatigue, drowsiness, muscle weakness, blunting of feelings, reduced alertness, confusion, headache, dizziness, ataxia and diplopia. These symptoms disappear with the continuation of treatment. Drug interaction: As with all psychoactive substances, the effect of Zepam[®] may be intensified by alcohol. Simultaneous intake of alcohol should be avoided. When Zepam[®] is combined with other centrally acting drugs such as antidepressants, hypnotic, narcotic analgesics, narcoleptics, anxiolytics/sedatives, antiepileptics, sedative antihistamines, or anesthetics, its CNS sedative effect may be increased.

General precautions

The patient should be checked regularly at the start of the treatment in order to minimize the dosage and/ or the frequency of administrations and to prevent overdose due to accumulation. Pregnancy and nursing mother: the safety of Bromazepam in pregnant women has not been established. Bromazepam should not be taken during pregnancy unless there is a compelling indications for its use and no safer therapeutic alternative is available. As benzodiazepines are excreted in breast milk, nursing mother should not take Zepam[®].

Contra-indications

Zepam[®] must not be administered to patients with known hypersensitivity to benzodiazepines, severe respiratory insufficiency or sleep apnea syndrome. Precautions: Dependence: The use of benzodiazepines and Benzodiazepine-like agents may lead to development of physical and psychological dependence upon these products. Withdrawal: once physical dependence has developed termination of treatment will be accompanied by withdrawal symptoms. These may consist of headache, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability. Amnesia: Anterograde amnesia may occur using higher therapeutic dosages (documented as 6 mg) the risk increasing at higher dosages. Duration of treatment: at the start of treatment it may be useful to inform the patient that the duration of treatment will be limited and that of dose will be tapered off at the end of treatment.

Overdosage

As with other benzodiazepines, intentional or accidental overdosage of Zepam[®] is seldom life threatening unless other CNS depressants (including alcohol) have been taken

simultaneously. Overdosage of benzodiazepines generally manifests itself in the form of CNS depression ranging from drowsiness to coma. Following overdose with oral benzodiazepines, vomiting should be induced (within 1 hour) if the patient is conscious or gastric lavage undertaken if the patient is unconscious. When no benefit is to be expected from evacuation of stomach, activated charcoal should be administered to reduce intestinal absorption.

Pharmaceutical precautions

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

Presentation

Zepam[®] 3mg tablet: round, light colored tablet with a breakline on one side embossed with 'ACI' in a circle. Each tablet contains Bromazepam BP 3mg.

Package quantities

Zepam[®] 3mg Tablet: Cartons of 100 tablets in Alu-Pvc blister.

® Registered Trade Mark



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