

SamBroTM 3mg Tablets (Bromazepam)

COMPOSITION:

SamBroTM 3mg Tablets

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

INDICATIONS AND USAGE:

SamBroTM (Bromazepam) is useful for the short-term, symptomatic relief of manifestations of excessive anxiety in patients with anxiety neurosis. Benzodiazepines are only indicated when the disorder is severe, disabling or subjecting the individual to extreme distress

Emotional disturbances: Acute tension and anxiety states, Difficulties in interpersonal contacts, agitation, insomnia, agitated depressive reactions

• **Functional disturbances:** Cardiovascular and respiratory systems: (Pseudoangina pectoris, precordial anxiety, emologenic hypertension tachycardia, dyspnea, hyperventilation)

• **Gastrointestinal system:** Irritable bowel syndrome, epigastric pain, spasm, bloating, diarrhoea etc.

• **Genitourinary system:** Frequency, irritable bladder and dysmenorrhoea

• **Psychosis disorders:** Psychogenic headache, psychogenic dermatosis, asthma, gastric and duodenal ulcer, ulcerative colitis, emotional reactions to chronic organic disease and adjuvant to psychotherapy in psychoneurosis

DOSAGE & ADMINISTRATION:

Average dose for ambulant therapy: 1.5 – 3mg three times daily

Severe cases especially in hospitals:

6 – 12mg two to three times daily. These are average recommendations and dosage should be individually determined. Treatment of ambulant patients in general begins with the lowest dose, gradually increasing if necessary to the optimum level. After about 8 to 12 weeks, according to progress in therapy, dosage can usually be reduced gradually and then stopped

OR

As directed by the physician

CONTRAINDICATIONS:

SamBroTM (Bromazepam) is contraindicated in patients with known hypersensitivity to benzodiazepines, myasthenia gravis, severe hepatic insufficiency, severe respiratory insufficiency or sleep apnea syndrome

SPECIAL PRECAUTIONS:

General Precautions:

The patient should be checked regularly at the start of treatment in order to minimize the dosage and/or the frequency of administration and to prevent overdose due to accumulation

Use in the elderly:

Elderly and debilitated patients or those with organic brain syndrome, have been found to be prone to CNS depression after even low doses of benzodiazepines. Therefore, medication should be initiated in these patients with very low initial doses and increments should be made gradually

Impaired Hepatic or Renal Function:

In patients with impaired hepatic or renal function, it is recommended to initiate therapy, if necessary, at a very low dose and to increase the dosage only to the extent that such an increase is compatible with the degree of residual function of these organs. Such patients should be followed closely & have periodic laboratory assessment

WARNINGS:

SamBroTM (Bromazepam) is not recommended for use in patients with depressive disorders or psychosis. Patients should be advised against the concurrent use of alcohol and other CNS depressant drugs. Patients with known or presumed dependence from alcohol or drugs should not take benzodiazepines, except in rare situations under medical supervision

Paediatric Use:

Because of the lack of sufficient clinical experience, Bromazepam is not recommended for use in patients less than 18 years of age

Driving and Hazardous Activities:

Since Bromazepam has a central nervous system depressant effect, patients should be warned against driving, operating dangerous machinery or engaging in other hazardous activities requiring mental alertness and physical co-ordination and should be cautioned that the effects of alcohol on such activities may be increased

Use in Pregnancy:

The safety of use of Bromazepam in pregnancy has not been established. Therefore, Bromazepam should not be used during pregnancy

Use by Nursing Mothers:

Bromazepam and its metabolites are probably excreted in human milk. Therefore, this drug should not be given to nursing mothers

CONTRAINDICATED ADVERSE EFFECTS:

The most frequently repeated adverse reactions with Bromazepam have been drowsiness, ataxia and dizziness. Some other side effects such as irritability, excitability, restlessness, agitation, delusion, rages, nightmares, hallucinations, psychosis, inappropriate behavior and other adverse behavioral effects are known to occur with the use of benzodiazepines

STABILITY:

See expiry on the pack

PRESENTATION:

SamBroTM 3mg tablets in a pack of 30's

INSTRUCTIONS:

Keep out of reach of children

For oral use only

Avoid exposure to heat, light and humidity

Store between 15 to 30°C

Improper storage may deteriorate the medicine



Manufactured by:
SAMI Pharmaceuticals (Pvt.) Ltd.
F-95, S.I.T.E., Karachi-Pakistan
www.samipharmapk.com

سامبروTM
سه ملی گرام ٹیبلٹ
(برومازیپام)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں
صرف کھانے کے لیے ہے

بچوں کی پہنچ سے دور رکھیں

دوا کو دھوپ، گرمی اور نمی سے محفوظ رکھیں۔ اسے ۱۵ سے ۳۰ ڈگری سینٹی گریڈ
کے درمیان میں رکھیں ورنہ دوا خراب ہو جائیگی