

# Calm

## Clobazam BP

### Presentation

**Calm 10 mg Tablet:** Each tablet contains Clobazam BP 10 mg.

### Description

The active ingredient of **Calm tablet** is clobazam. Chemically Clobazam is a derivative of benzodiazepine. It has a sustained anxiolytic action and is widely used for the relief of acute or chronic anxiety, tension and agitation.

### Pharmacology

Clobazam is readily and completely absorbed from the gastro-intestinal tract and peak plasma concentration occurs within about 30 to 90 minutes after oral administration. The drug is generally widely distributed into body tissues and cross the blood brain barrier. The drug and its metabolites is highly bound to the plasma protein. Clobazam is extensively metabolized in the liver. It is excreted in the urine mainly in the form of its metabolites. The action of Clobazam results from the activity on the central nervous system. It directly acts on amygdala in the limbic system, the main seat of anxiety and tension. **Calm tablet** produces its effect by suppressing the amygdala.

### Indications

Clobazam (**Calm tablet**) is indicated for the relief of acute and chronic anxiety states, which may produce the following symptoms in particular: Anxiety, tension, restlessness, excitement, irritability, sleep disturbances from emotional causes, psychovegetative and psychosomatic disorders (for example, in the cardiovascular or gastro-intestinal area) and emotional instability. **Calm tablet** may be used together with antidepressants in treatment of anxiety associated with depression. It may also be indicated as adjunctive therapy in patients with epilepsy, who are not adequately stabilized with their anticonvulsant monotherapy.

### Dosage and Administration

The initial dose should be as low as possible. This is the fundamental principle for Clobazam.

**Treatment of anxiety state:** The initial dose is usually 2 **Calm tablets** daily. If necessary, the daily dose may be increased to 3 tablets.

*For elderly patients,* total daily dose is 10 - 15 mg.

*For children between 3 and 15 years of age,* daily dose is 5 - 10 mg. After improvement of the symptoms, the dose may be reduced. After prolonged treatment, **Calm tablet** should not be withdrawn suddenly. Otherwise, symptoms such as restlessness, anxiety and insomnia may occur. Here, the dose should be reduced gradually under medical supervision.

#### **Treatment of epilepsy:**

*Adults and adolescents over 15 years of age:* The initial dose is 10 - 15 mg daily, it may be gradually increased to maximum 80 mg daily. Furthermore, constant doses (e.g. 20mg/ day) and intermittent therapy have proved effective.

*Children from 3 to 15 years of age:* Starting with 5 mg dose and maintenance dose of 0.3 - 1.0 mg/Kg body weight daily is enough for treatment with one or more other anti epileptic drugs.

### Contraindication

Clobazam (**Calm tablet**) should not be used to patients, who have hypersensitivity to clobazam or any of the excipients, or who have a history of drug dependence. It should not be used in the first trimester of pregnancy, and in the later stages only if there are compelling indications for use it. **Calm tablet** should not be taken by nursing mother, since it passes into the breast milk. If there are compelling indications for its use, breast-feeding should be stopped. Children between the ages of 6 months and 3 years should not normally be given **Calm tablet**. The drug is not suitable for patients with respiratory depression and myasthenia gravis.

### Precautions

**Calm tablet** should be administered with caution in patients with hepatic or renal impairment. The ability to operate or drive a car may be impaired in patients sensitive to **Calm tablet** or in patients taking high doses.

### Use in Pregnancy and Lactation

*Pregnancy:* **Calm tablet** should not be used in pregnancy.

*Nursing mothers:* **Calm tablet** should not be given to nursing mother as the drug appears in the breast milk.

### Side effects:

**Calm tablet** is generally well tolerated. The most frequently observed side effects, particularly during the initial phase of therapy include drowsiness, ataxia, fatigue, confusion and vertigo. These may diminish with continued therapy. Occasionally dry mouth; headache, hypersensitivity reactions and respiratory depression may occur.

### **Drug Interaction**

Clobazam may potentiate the effects of CNS depressants such as alcohol, analgesics, sedatives & hypnotics and neuroleptic drugs when taken concomitantly. Clobazam may increase the plasma concentration of valproic acid when **Calm tablet** is used simultaneously with anticonvulsant in the treatment of epilepsy. The effects of muscle relaxants, analgesics and nitrous oxide may be enhanced. Carbamazepine and phenytoin increase the metabolism of Clobazam. Concurrent treatment with cimetidine may enhance and prolong the action of clobazam.

### **Overdosage**

Higher doses should always be avoided. As the dose of **Calm tablet** is increased, sedation progress to hypnosis and then to stupor. Gastric lavage may be useful to remove the ingested drug or if necessary the patient may be hospitalized.

### **Legal Warning**

To be sold and dispensed only on the prescription of a registered physician. Keep out of reach of children.

### **Pharmaceutical Precaution**

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

### **Commercial Pack**

**Calm 10 mg Tablet:** Each Box containing 10 blister pack of 10 tablets.

*Manufactured by*



For further query on the use of this medicine, consult to a registered Doctor or Pharmacist.