CLOBATOR

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

Abbreviated Prescribing information for CLOBATOR (Clobazam 5 mg and 10 mg Tablets) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Clobazam is a long-acting 1,5-benzodiazepine.
INDICATION: In the treatment of epilepsy and short-term treatment of acute anxiety.
DOSAGE AND ADMINISTRATION: Treatment of anxiety: The usual anxiolytic dose for adults and adolescents over 15 years of age is 20-30 mg daily in divided doses or as a single dose given at night. The lowest dose that can control symptoms should be used. After improvement of the symptoms, the dose may be reduced. Treatment of epilepsy: In epilepsy a starting dose of 20-30 mg/day is recommended, increasing as necessary up to a maximum of 60 mg daily.
CONTRAINDICATION: In the patients who are having hypersensitivity to benzodiazepines or any of the excipients of Clobator. In patients with any history of drug or alcohol dependence. In patients with myasthenia gravis, severe respiratory insufficiency, sleep apnoea syndrome, severe hepatic insufficiencies. During the first trimester of pregnancy, In breast-feeding women. Clobazam must not be used in children between the ages of 6 months and 3 years, other than in exceptional cases.
WARNINGS & PRECAUTIONS: Amnesia may occur. In case of loss or bereavement psychological adjustment may be inhibited by benzodiazepines. Special caution is necessary if clobazam is used in patients with myasthenia gravis, spinal or cerebellar ataxia or sleep apnoea. Suicide may be precipitated in patients who are depressed and aggressive behaviour towards self and others may be precipitated. Use of clobazam may lead to the development of physical and psychic dependence. The risk of dependence increases with dose and duration of treatment. Respiratory function should be monitored in patients with chronic or acute severe respiratory insufficiency. In long-term treatment renal and hepatic function must be checked regularly. Caution required for serious dermatological reaction (Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis)
DRUG INTERACTION: Central depressive effect may occur in cases of concomitant use with antipsychotics (neuroleptics), hypnotics, anxiolytics/sedatives, antidepressant agents, narcotic analgesics, anticonvulsant drugs, anaesthetics and sedative antihistamines. Concomitant consumption of alcohol can increase the bioavailability of clobazam by 50%. Addition of clobazam to established anticonvulsant medication (e.g., phenytoin, valproic acid) may cause a change in plasma levels of these drugs. If clobazam is used concomitantly with narcotic analgesics, possible euphoria may be enhanced.
ADVERSE REACTIONS: Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis, sedation leading to fatigue and sleepiness, drowsiness, dizziness or dryness of the mouth, constipation, loss of appetite, nausea, fine tremor of the fingers. Restlessness, irritability, difficulty in sleeping, anxiety, delusion, nightmare, hallucinations or suicidal tendencies, Anterograde amnesia, respiratory depression, ataxia, confusion, headaches, Disorders of articulation, unsteadiness of gait and other motor functions, visual disorders (e.g., double vision), weight gain, loss of libido, impairment of consciousness, muscle weakness. Tolerance and physical and/or psychic dependence may develop, especially during prolonged use.

MARKETED BY:

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(Additional information is available on request)