Leptic®

Tablet/ Orally Disintegrating Tablet

Clonazepam USP

Composition

Leptic® 0.5: Each tablet contains Clonazepam USP 0.5 mg.
Leptic® 1: Each tablet contains Clonazepam USP 1 mg.
Leptic® 2: Each tablet contains Clonazepam USP 2 mg.
Leptic® 0.25 ODT: Each orally disintegrating tablet contains Clonazepam USP 0.25 mg.
Leptic® 0.5 ODT: Each orally disintegrating tablet contains Clonazepam USP 0.5 mg.

Pharmacology

Leptic® (Clonazepam) is available as scored tablets containing 0.5 mg, 1 mg, 2 mg & as ODT containing 0.25 mg, 0.5 mg Clonazepam USP. Chemically, Clonazepam is a benzodiazepine derivative. It exhibits several pharmacologic properties, which are characteristics of the benzodiazepine class of drugs. In human it is capable of suppressing the spike and wave discharge in absence seizure (petit mal) and decreasing the frequency, amplitude, duration and spread of discharge in minor motor seizure.

Indications

✓ All clinical forms of epileptic disease & seizures in infants, children & adults, especially absence seizures including :
- atypical absence
- primary & secondarily generalized tonic-clonic (grand mal)
- tonic-clonic seizures
- partial (focal) seizures with elementary or complex symptomatology
- various forms of myoclonic seizures
- myoclonus & associated abnormal movements

✓ Panic disorder with or without a goraphobia
✓ Insomnia

Dosage & Administration

Route of Administration : Oral.

Indication	Patient Category	Recommended dose		
		Initial dosage	**Increment dosage**	**Maximum dosage**
Seizure Disorders	Adults	The initial dose for adults with seizure disorders should not exceed 1.5 mg/day divided into three doses.	Dosage may be increased in increments of 0.5 to 1 mg every 3 days until seizures are adequately controlled or until side effects preclude any further increase.	Maximum recommended daily dose is 20 mg.
	Pediatric Patients	The initial dose for infants and children (up to 10 years of age or 30 kg of body weight) should be between 0.01 and 0.03 mg/kg/day but not to exceed 0.05 mg/kg/day given in two or three divided doses.	Dosage should be increased by no more than 0.25 to 0.5 mg every third day until a daily maintenance dose of 0.1 to 0.2 mg/kg of body weight has been reached, unless seizures are controlled or side effects preclude further increase.	0.05 mg/kg/day
	Geriatric Patients	In general, elderly patients should be started on low doses of Clonazepam and observed closely.	-	20 mg/day
Panic Disorder	Adults	The initial dose for adults with panic disorder is 0.25 mg twice daily.	An increase to the target dose for most patients of 1 mg/day may be made after 3 days. The recommended dose of 1 mg/day is based on the results from a fixed dose study in which the optimal effect was seen at 1 mg/day.	20 mg/day
	Pediatric Patients	There is no clinical trial experience with Clonazepam in panic disorder patients under 18 years of age	-	-
	Geriatric Patients	In general, elderly patients should be started on low doses of Clonazepam and observed closely.	-	20 mg/day
Insomnia	Adults	Doses of 0.25 to 0.5 mg PO at bedtime have been suggested.	-	20 mg/day
	Geriatric Adults	Doses of 0.25 to 0.5 mg PO at bedtime have been suggested for younger adults.	-	20 mg/day

Initial dosage should be low and increased gradually to a maintenance dosage that controls seizure without toxic effects. During discontinuation, the dosage should be tapered.
Or as directed by the physician.

Contraindications

Clonazepam should not be used in patients with a history of sensitivity to benzodiazepine, nor in patients with clinical or biochemical evidence of significant liver disease. It may be used in patients with open angle glaucoma who are receiving appropriate therapy but is contraindicated in acute narrow angle glaucoma.

Warning & Precautions

When used in patients in whom several different types of seizure disorders coexist, Clonazepam may increase the incidence or precipitate the onset of generalized tonic-clonic seizures (grand mal). This may require the addition of appropriate anticonvulsants

or an increase in their dosages. The concomitant use of Valproic acid and Clonazepam may produce absence status. Periodic blood counts and liver function tests are advisable during long term therapy with Clonazepam.
The abrupt withdrawal of Clonazepam, particularly in those patients on long-term, high-dose therapy, may precipitate status epilepticus. Therefore when discontinuing Clonazepam, gradual withdrawal is essential.
Clonazepam may produce an increase in salivation. This should be considered before giving the drug to patients who have difficulty handling secretions. Because of this and the possibility of respiratory depression, Clonazepam should be used with caution in patients with chronic respiratory diseases.
Because of the possibility that adverse effect on physical or mental development could become apparent only after many years, a benefit-risk consideration of the long-term use of Clonazepam is important in pediatric patients.

Side effects
Common side effects: The most frequently occurring side effects of Clonazepam are referable to CNS depression, drowsiness, fatigue, dizziness, muscle hypotonia, co-ordination disturbance, hypersalivation in infants, paradoxical aggression, irritability and mental change.
Rare side effects: Skin rash, angioedema, hemolytic anemia, abnormal liver function tests, decreased lung function and coma.

Use in pregnancy and lactation
The use of Clonazepam during pregnancy or lactation should be avoided. Clonazepam is excreted into the breast milk and should therefore be avoided in breast-feeding mothers.

Use in children & Adolescents
This medication hasn't been studied in children with panic disorders. It shouldn't be used for the treatment of this condition in people younger than 18 years.

Drug Interactions
With Medicine: The CNS-depressant action of the benzodiazepine class of drugs may be potentiated by alcohol, narcotics, barbiturates, nonbarbiturate hypnotics, antianxiety agents, the phenothiazines, thioxanthene and butyrophenone classes of antipsychotic agents, monoamine oxidase inhibitors, tricyclic antidepressants and by other anticonvulsant drugs.
With food & others: No interaction with food.

Overdose
Symptoms of Clonazepam overdosage, like those produced by other CNS depressants, include somnolence, confusion, coma and diminished reflexes.

Storage
Store below 30^0 C temperature and dry place, protected from light.
Keep all medicines out of reach of children.

Packing
Leptic® 0.5: Each box contains 5x10 & 10x10 tablets in Alu-PVC/PVDC blister strips.
Leptic® 1: Each box contains 3x10 & 5x10 tablets in Alu-PVC/PVDC blister strips
Leptic® 2: Each box contains 3x10 & 5x10 tablets in Alu-PVC/PVDC blister strips.
Leptic® 0.25 ODT: Each box contains 3x10 orally disintegrating tablets in Alu-Alu blister strips.
Leptic® 0.5 ODT: Each box contains 3x10 orally disintergrating tablets in Alu-Alu blister strips.

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* Further information is available on request.

Manufactured by:
The ACME Laboratories Ltd.
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For Health, Vigour and Happiness