

Denixil[®]

Clonazepam USP

Presentation

Denixil[®] 0.5 mg : Each tablet contains Clonazepam USP 0.5mg

Denixil[®] 2mg : Each tablet contains Clonazepam USP 2mg

Description

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 and Uses

1. Panic attack
2. Epilepsy
 - Status epilepticus
 - Lennox-Gastaut syndrome
 - Infantile spasm
 - Absence seizure
 - Myoclonic seizure
 - Tonic-clonic seizure
 - Akinetic and atonic seizure
 - Partial seizure
3. Bipolar affective disorder
4. Drug-induced dyskinesia
5. Choreiform movement
6. Fulgurant pain
7. Tourette's syndrome
8. Resistant depression
9. Nocturnal myoclonus
10. Trigeminal neuralgia

Dosage and Administration

Infants and children

Initial dose: 0.01- 0.03mg/kg/day	Up to 1 year: 0.25mg daily in divided dose, not to exceed 0.05mg/kg/day increase gradually to 0.5- 1mg.
Increment dose: not more than 0.25- 0.5mg at intervals of 3 days	1- 5 years: 0.25mg daily in divided dose, at intervals of 3 days increase to 1- 3 mg.
Maintenance dose: 0.1 - 0.2mg/kg /day Dosing interval: b.i.d. / t.i.d.	5- 12 years: 0.5mg daily in divided dose, increase to 3-6mg

Adults and elderly

Initial dose: 1 mg daily in divided dose (Elderly 0.5 mg), not to exceed 1.5mg/day

Increment dose: 0.5 - 1mg at intervals of 3 days

Maintenance dose: 4 - 8mg/day

Maximum dose: 20mg/day should be administered with caution

Dosing interval: b.i.d. / t.i.d.

Initial dose should be low and increased gradually to a maintenance dose that controls seizure

without toxic effects. During discontinuation, the dose should be tapered.

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.

Use in pregnancy & 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.

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 effects 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.

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.

Drug interactions

The CNS- depressant action of the benzodiazepine class group may be potentiated by alcohol, narcotics, barbiturates, non barbiturate hypnotics, anti-anxiety agents, the phenothiazines, thioxanthene and butyrophenone classes of antipsychotic agents, monoamine oxidase inhibitors and tricyclic antidepressants and by other anticonvulsant drugs.

Over dosage

Symptoms of clonazepam over dosage, like those produced by other CNS depressants, include somnolence, confusion, coma and diminished reflexes.

Commercial Pack

Denixil[®] 0.5mg: Each box contains 5x10 tablets in ALU-PVC blister.

Denixil[®] 2mg: Each box contains 3x10 tablets in ALU-PVC blister.

Storage Conditions

Store in a cool and dry place, away from light and children. Do not use after the expiry date stated on the package.



Manufactured by
Renata Limited
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®Trade Mark

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Size : 75 x 145 mm