Epiclon

Clonazepam Tablet

Presentation :
Epiclon 2 : Each tablet contains Clonazepam USP 2 mg.
Epiclon 0.5 : Each tablet contains Clonazepam USP 0.5 mg.

Description :
Chemically, Clonazepam is 5-(2-chlorophenyl)-1,3-dihydro-7-nitro-2H-1,4-benzodiazepin-2-one. Clonazepam exerts its antiseizure and antipanic effects by enhancing the activity of gamma aminobutyric acid (GABA), the major inhibitory neurotransmitter in the central nervous system. In humans, clonazepam is capable of suppressing the spike and wave discharge in absence seizures (petit mal) and decreasing the frequency, amplitude, duration, and spread of discharge in minor motor seizures.

Indications :

1. Panic disorder
2. Drug induced dyskinesias
3. Choreiform movements
4. Fulgurant pain
5. Bipolar affective disorder
6. Epilepsy
   a) Status epilepticus
   b) Lennox Gastaut Syndrome
   c) Infantile spasms
   d) Absences
   e) Tonic- clonic, Myoclonic & Partial seizures

Dosage and Administration :
Panic disorder :
Adults : Initial dose-the recommended initial dosage of Clonazepam is 0.25 mg twice daily. Increment dose- 0.5-1mg at interval of 3 days. To reduce the inconvenience of somnolence, administration of one dose at bedtime may be desirable.

Pediatric patients : There is no clinical trial experience with Clonazepam in Panic disorder patients under 18 years of age.

Seizure disorder (Epilepsy) :
Adults : initial dose- 1 mg daily in divided dose (elderly 0.5 mg). Not to exceed 1.5 mg/day. Increment dose- 0.5-1 mg at intervals of 3 days. Maintenance dose- 4-8 mg/day. Maximum dose- 20 mg/day should be administered with caution.
Child : Up to 1 year - 0.25 mg increased as above to 0.5-1 mg.
1- 5 years - 0.25 mg increased to 1- 3 mg
5- 12 years - 0.5 mg increased to 3 - 6 mg.

Contraindications :
Clonazepam must not be used in patients with known hypersensitivity to benzodiazepines, acute pulmonary insufficiency and respiratory depression.

Precautions :
The dosage of Clonazepam must be carefully adjusted to individual requirements in elderly patients, patients with preexisting disease of the respiratory system (chronic obstructive pulmonary disease), liver or kidneys and in patients undergoing treatment with other centrally acting medications or anticonvulsant agents. Like all drugs of this type, Clonazepam may, depending on dosage, administration and individual susceptibility, modify the patient's reactions (driving ability, behavior in traffic).

Clonazepam should be withdrawn slowly and abrupt discontinuance of the drug should be avoided, especially during long-term, high-dose therapy to avoid precipitating seizures, status epilepticus, or withdrawal symptoms.

Side effects :
The following undesirable effects occur relatively frequently: fatigue, drowsiness, muscular hypotonia, dizziness, light-headedness and ataxia. These effects are usually transient and generally disappear spontaneously in the course of the treatment or on reduction of the dosage. They can be partially prevented by increasing the dose slowly at the start of treatment.

Use in pregnancy & lactation :
During pregnancy : Should avoid regular use (risk of neonatal withdrawal symptoms); use only if clear indication such as seizure control (high doses during late pregnancy or labour may cause neonatal hypothermia, hypotonia and respiratory depression).
During lactation : Clonazepam should be avoided during lactation because it passes into the breast milk.

Special conditions :
Paediatrics : Safety and effectiveness in pediatric patients with panic disorder below the age of 18 have not been established.
Geriatrics : Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.
Renal Impairment : Clonazepam should be administered with caution in patients with impaired renal function.
Hepatic Impairment : Clonazepam should be administered with caution in patients with impaired hepatic function.

Drug Interactions :
Concurrent administration of hepatic enzyme inducers such as carbamazepine, phenobarbitone or phenytoin, may accelerate the metabolism of Clonazepam. Concomitant intake of alcohol may affect the patient's response to Clonazepam. Clonazepam may be expected to have the sedative interaction associated with benzodiazepines in general.

Storage conditions :
Store below 25°C, protect from direct sunlight & heat.

Shelf-life :
3 years from the date of manufacturing.

Commercial Pack :
Epiclon 2 : Each box contains 3 blister packs of 10 tablets.
Epiclon 0.5 : Each box contains 5 blister packs of 10 tablets.

general GENERAL
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