

Clonafix

Clonazepam USP

COMPOSITION:

Clonafix 0.5 : Each tablet contains Clonazepam USP 0.5 mg.
Clonafix 2 : Each tablet contains Clonazepam USP 2 mg.

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:

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 - 0.03 mg/kg/day not to exceed 0.05 mg/kg/day
- *Increment dose:* not more than 0.25 - 0.5 mg at intervals of 3 days
- *Maintenance dose:* 0.1 - 0.2 mg/kg/day
- *Dosing interval:* Two times or three times a day.
- *Up to 1 year:* 0.25 mg daily in divided dose, increase gradually to 0.5 - 1 mg.
- *1 - 5 years:* 0.25 mg daily in divided dose, increase to 1 - 3 mg.
- *5 - 12 years:* 0.5 mg daily in divided dose, increase to 3 - 6 mg.

Adults and elderly

- *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
- *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.

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.

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.

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 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.

DRUG INTERACTIONS:

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 and the tricyclic antidepressants, and by other anticonvulsant drugs.

OVERDOSAGE:

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

STORAGE:

Store below 30°C Temperature in a dry place. Keep away from light. Keep out of the reach of children.

PACKING:

Clonafix 0.5 : Each box contains 3 x 10 tablets in blister strips.
Clonafix 2 : Each box contains 3 x 10 tablets in blister strips.

Manufactured by:

Novatek Pharmaceuticals Ltd.

Gilarchala, 7 Kewa Mouza, Sreepur, Gazipur, Bangladesh.

NOVATEK