

# Esypan<sup>®</sup>

## Clonazepam Tablet & Drops

### Presentation

Esypan<sup>®</sup> 0.5: Each film coated tablet contains Clonazepam USP 0.5 mg.  
Esypan<sup>®</sup> 2: Each film coated tablet contains Clonazepam USP 2 mg.  
Esypan<sup>®</sup> Drops: Each 5 ml drops contains Clonazepam USP 12.5 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 and Uses

- Panic attack
- Epilepsy
- Bipolar affective disorder
- Drug-induced dyskinesia
- Lennox-Gastaut syndrome
- Status epilepticus
- Infantile spasm
- Fulgurant pain
- Tourette's syndrome
- Absence seizure
- Myoclonic seizure
- Tonic-clonic seizure
- Akinetic and atonic seizure
- Partial seizure
- Nocturnal myoclonus
- Resistant depression
- Trigeminal neuralgia

### 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.

### Dosage And Administration

#### Infants and children

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

#### 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.*

### Use in Pregnancy & lactation

Patients should be advised to notify their physician if they become pregnant or intend to become pregnant during therapy with Esypan. Patients should be advised not to breastfeed an infant if they are taking Esypan.

### 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.

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.

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.

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, coordination disturbance, hypersalivation in infants, paradoxical aggression, irritability and mental change.

### Drug Interaction

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

### Overdoses

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

### Commercial Pack

Esypan<sup>®</sup> 0.5: Each box contains 5 blister strips of 10 tablets.  
Esypan<sup>®</sup> 2: Each box contains 5 blister strips of 10 tablets.  
Esypan<sup>®</sup> Drops: Each bottle contains 10 ml drops.

Manufactured by :  
 **Silva**  
Pharmaceuticals Limited  
Maljdee, Noakhali, Bangladesh