

# Epitra®

## Clonazepam USP

### COMPOSITION

- Epitra® 0.5 tablet** : Each tablet contains Clonazepam USP 0.5 mg.  
**Epitra® 2 tablet** : Each tablet contains Clonazepam USP 2 mg.  
**Epitra® Oral Drops** : Each ml drop contains Clonazepam USP 2.5 mg.

### PHARMACOLOGY

Clonazepam has pharmacological properties characteristic of the benzodiazepine class of drugs. Clonazepam has sedative, hypnotic and anticonvulsant properties. Its basic anticonvulsive properties are also similar to those of other benzodiazepines.

### INDICATION

- Anxiety as well as panic disorder, with or without agoraphobia.
- Epilepsy and other seizure disorders.
- Alone or as an adjunct in the management of myoclonic and akinetic seizures and petit mal variant (Lennox-Gastaut syndrome). May also be of some value in patients with absence spells (petit mal) who have failed to respond to succinimides.

### DOSAGE & ADMINISTRATION

Dosage must be determined in each patient according to clinical response and tolerance.

**Children** : 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 and should not exceed 0.05 mg/kg/day given in two or three divided doses. Dosage should be increased by not more than 0.25 to 0.50 mg every third day until a 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. Whenever possible, the daily dose should be divided into three equal doses. If doses are not equally divided, the larger dose should be given before retiring. **Adults** : The initial dose for adults should not exceed 1.5 mg/day divided into three doses. \*Dosage may be increased in increments of 0.5 to 1 mg every three days until seizures are adequately controlled. Maintenance dosage must be individualized for each patient depending upon response. A recommended maintenance dose for adults is 8 to 10 mg/day in three divided doses. Dosages in excess of 20 mg/day should be administered with caution. The use of multiple anticonvulsants may result in an increase of depressant adverse effects. This should be borne in mind whenever Clonazepam is added to an already existing anticonvulsant regimen.

### CONTRAINDICATION

Significant liver disease, narrow angle glaucoma, sensitivity to benzodiazepines.

### PRECAUTIONS

Although simultaneous administration of several anticonvulsants may be considered with clonazepam, such combined therapy may result in an increase of central depressant adverse effects. When used in patients in whom several different types of seizures co-exist, clonazepam may increase the incidence or precipitate the onset of generalized tonic-clonic seizures (grand mal).

### PREGNANCY & LACTATION

Pregnancy category is 'C'. The use of clonazepam during pregnancy should be avoided. Mothers receiving clonazepam should not breast feed their infants.

### SIDE EFFECT

The most frequently occurring adverse reactions to clonazepam are referable to CNS depression, drowsiness, ataxia. In some cases, these may diminish with time. Behaviour problems and salivation have been noted.

### DRUG INTERACTION

Interactions have been reported between some benzodiazepines and other anticonvulsants, with changes in the serum concentration of the benzodiazepine or anticonvulsant.

### OVERDOSE

The cardinal manifestations of overdosage are drowsiness and confusion, reduced reflexes and coma. There are minimal effects on respiration, pulse and blood pressure, unless the overdosage is extreme.

### STORAGE

**Epitra®** tablet should be stored in a cool & dry place, protected from light & moisture.  
**Epitra®** oral drops should be stored in a cool & dry place, protected from light.  
Keep out of reach of children.

### HOW SUPPLIED

- Epitra® 0.5 tablet** : Each box contains 10 x 10 tablets in blister pack.  
**Epitra® 2 tablet** : Each box contains 5 x 10 tablets in blister pack.  
**Epitra® Oral Drops** : Each bottle contains 10 ml oral drops.

Manufactured by :



**SQUARE**  
PHARMACEUTICALS LTD.  
BANGLADESH

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