

COMPOSITION

Epitra* 0.5 mg tablet: Each tablet contains Clonazepam USP 0.5 mg. **Epitra*** 1 mg tablet: Each tablet contains Clonazepam USP 1 mg. **Epitra*** 2 mg tablet: Each tablet contains Clonazepam USP 2 mg.

PHARMACOLOGY

Clonazepam has pharmacological properties 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.

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.

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. Behavioral problems and salivation have been noted.

DRUG INTERACTION

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

PREGNANCY & LACTATION

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

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

Store below 30° C. Keep away from light. Keep all the medicine out of reach of children.

HOW SUPPLIED

Epitra[®] 0.5 tablet: Box containing 50 tablets in blister pack. **Epitra**[®] 1 tablet: Box containing 60 tablets in blister pack. **Epitra**[®] 2 tablet: Box containing 60 tablets in blister pack.

Manufactured by

