



Presentation

Clonapin® 0.5 Tablet: Each tablet contains 0.5 mg Clonazepam BP.
Clonapin® 1 Tablet: Each tablet contains 1 mg Clonazepam BP.
Clonapin® 2 Tablet: Each tablet contains 2 mg Clonazepam BP.

Pharmacology/Description

Clonazepam is an anti-seizure and anti-panic medication in the benzodiazepine family. Clonazepam acts by enhancing the effects of gamma-aminobutyric acid (GABA) in the brain.

Indication

Clonazepam is used for ● Anxiety disorders (Generalized, Phobic & Panic disorders) ● Insomnia and sleep disturbances ● Labile arterial hypertension ● Peri and Post-menopausal anxiety (Anxiety in middle aged women) ● Burning Mouth Syndrome ● Postoperative anxiety disorder ● Post traumatic stress disorder ● Anxiety in cancer patient (palliative treatment) ● Restless legs syndrome (RLS) ● Nocturnal myoclonus ● Tourette's syndrome ● Bipolar affective disorder ● Resistant depression ● Choreiform movement ● Epilepsy

Dosage And Administration

Seizure Disorders: Adults: Clonazepam is administered orally. The initial dose for adults with seizure disorders should not exceed 1.5 mg/day divided into three doses. Dosage may be increased in increments of 0.5 to 1 mg every 3 days until seizures are adequately controlled or until side effects preclude any further increase. Maintenance dosage must be individualized for each patient depending upon response. Maximum recommended daily dose is 20 mg. The use of multiple anticonvulsants may result in an increase of depressant adverse effects. This should be considered before adding Clonazepam to an existing anticonvulsant regimen.

Pediatric Patients: Clonazepam is administered orally. In order to minimize drowsiness, 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 but not to exceed 0.05 mg/kg/day given in two or three divided doses. Dosage should be increased by no more than 0.25 to 0.5 mg every third day until a daily 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 largest dose should be given before retiring.

Geriatric Patients: There is no clinical trial experience with Clonazepam in seizure disorder patients 65 years of age and older. In general, elderly patients should be started on low doses of Clonazepam and observed closely

Panic Disorder: Adults: The initial dose for adults with panic disorder is 0.25 mg bid. An increase to the target dose for most patients of 1 mg/day may be made after 3 days. The recommended dose of 1 mg/day is based on the results from a fixed dose study in which the optimal effect was seen at 1 mg/day. Higher doses of 2, 3 and 4 mg/day in that study were less effective than the 1 mg/day dose and were associated with more adverse effects. Nevertheless, it is possible that some individual patients may benefit from doses of up to a maximum dose of 4 mg/day, and in those instances, the dose may be increased in increments of 0.125 to 0.25 mg bid every 3 days until panic disorder is controlled or until side effects make further increases undesired. To reduce the inconvenience of somnolence, administration of one dose at bedtime may be desirable. Treatment should be discontinued gradually, with a decrease of 0.125 mg bid every 3 days, until the drug is completely withdrawn. There is no body of evidence available to answer the question of how long the patient treated with clonazepam should remain on it. Therefore, the physician who elects to use Clonazepam for extended periods should periodically reevaluate the long-term usefulness of the drug for the individual patient.

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

Geriatric Patients: There is no clinical trial experience with Clonazepam in panic disorder patients 65 years of age and older. In general, elderly patients should be started on low doses of Clonazepam and observed closely

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.

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.

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, thioxanthine and butyrophenon classes of antipsychotic agents, monoamine oxidase inhibitors and the tricyclic antidepressant and other anticonvulsant drugs.

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. In addition, the dosage of each drug may be required to be adjusted to obtain the optimum effect. Abrupt withdrawal of Clonazepam particularly in those patients on long-term, high dose therapy, may precipitate status epilepticus. Therefore, as with any other anticonvulsants, gradual withdrawal is essential when discontinuing Clonazepam. While Clonazepam is being gradually withdrawn, the simultaneous substitution of incremental doses of another anticonvulsant may be indicated. 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 mother. Occupational hazards: Patients receiving Clonazepam should be in caution during hazardous occupations requiring complete mental alertness, such as operating machinery or driving a motor vehicle. They also should be warned against the concomitant use of alcohol and other CNS depressant drugs.

Overdosage:

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

Pharmaceutical Precautions

Store in cool dry place protected from light. Keep out of reach of children.

Commercial Pack

Clonapin® 0.5 Tablet: Box containing 3 X 10 tablets in blister pack.
Clonapin® 1 Tablet: Box containing 3 X 10 tablets in blister pack.
Clonapin® 2 Tablet: Box containing 3 X 10 tablets in blister pack.

Manufactured by :



POPULAR PHARMACEUTICALS LTD.
TONGI, GAZIPUR, BANGLADESH