

COMPOSITION

Pandura 0.5 Tablet: Each tablet contains Clonazepam BP 0.5 mg.

Pandura 1 Tablet: Each tablet contains Clonazepam BP 1 mg.

Pandura 2 Tablet: Each tablet contains Clonazepam BP 2 mg.

PHARMACOLOGY

Clonazepam is a benzodiazepine. It has sedative, hypnotic and anticonvulsant properties. Its mechanism of action is believed to be related to its ability to enhance the activity of gamma aminobutyric acid (GABA), the major inhibitory neurotransmitter in the central nervous system. It is rapidly and completely absorbed after oral administration.

INDICATIONS

It is indicated for the treatment of panic disorder, with or without agoraphobia. Panic disorder is characterized by the occurrence of unexpected panic attacks and associated concern about having additional attacks, worry about the implications or consequences of the attacks.

It is also indicated alone or as an adjunct in the treatment of the Lennox-Gastaut Syndrome (petit mal variant), akinetic and myoclonic seizures. It may be indicated in patients with absence seizures (petit mal) who have failed to respond to succinimides.

The effectiveness of Clonazepam in long-term use, that is, for more than 9 weeks, has not been systematically studied in controlled clinical trials. The physician who elects to use Clonazepam for extended periods should periodically reevaluate the long-term usefulness of the drug for the individual patient.

DOSAGE AND ADMINISTRATION

Adults: 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 initial dose for adults with panic disorder is 0.25 mg given in two divided dose. An increase to the target dose for most patients of 1 mg/day may be made after 3 days.

Pediatric Patients: 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.

CONTRAINDICATIONS

It should not be used in patients with a history of hypersensitivity to benzodiazepines, 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.

WARNING AND PRECAUTION

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. 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.

SIDE EFFECTS

The most frequently occurring side effects of Clonazepam are referable to CNS depression. Experience in treatment of seizures has shown that drowsiness has occurred in approximately 50% of patients and ataxia in approximately 30%. In some cases, these may diminish with time; behavior problems have been noted in approximately 25% of patients. Abnormal eye movements, aphonia, coma, tremor, vertigo, confusion, depression, amnesia, hallucinations, hysteria, increased libido, insomnia, psychosis and palpitations may also occur.

USE IN PREGNANCY AND LACTATION

Clonazepam should be used in pregnancy only if the potential benefits outweigh the potential risk to the fetus and it is recommended that women receiving Clonazepam should not breast feed.

USE IN CHILDREN AND ADOLESCENTS

Safety and effectiveness in pediatric patients below the age of 18 have not been established.

DRUG INTERACTIONS

Clonazepam does not appear to alter the pharmacokinetics of phenytoin, carbamazepine or phenobarbital. The effect of Clonazepam on the metabolism of other drugs has not been investigated.

OVERDOSAGE

Symptoms of Clonazepam overdose include somnolence, confusion, coma and diminished reflexes. Treatment includes monitoring of respiration, pulse and blood pressure, general supportive measures and immediate gastric lavage.

STORAGE

Store below 30°C temperature in dry place. Protect from light. Keep out of the reach of children.

HOW SUPPLIED

Pandura 0.5 Tablet: Each box contains 50 tablets in Alu-PVDC blister pack.

Pandura 1 Tablet: Each box contains 50 tablets in Alu-PVDC blister pack.

Pandura 2 Tablet: Each box contains 30 tablets in Alu-PVDC blister pack.