

Pandura

Clonazepam BP

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.

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.

INDICATION

It is 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.

It is also 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.

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

Infants and children:

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

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.

SIDE EFFECT

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 & palpitations may also occur.

CONTRAINDICATION

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.

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.

DRUG INTERACTION

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.

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.

STORAGE CONDITION

Keep in a dry place away from light and heat. 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.

Manufactured by:

NIPRO JMI Pharma Ltd.

Chaudhogram, Comilla, Bangladesh.