

Arotril®

Clonazepam USP 0.5, 1 & 2 mg

Composition:

Arotril® 0.5 mg Tablet: Each tablet contains Clonazepam USP 0.5 mg.

Arotril® 1 mg Tablet: Each tablet contains Clonazepam USP 1 mg.

Arotril® 2 mg Tablet: Each tablet contains Clonazepam USP 2 mg.

Pharmacology:

Arotril® (Clonazepam), a derivative of benzodiazepine is mainly used as anticonvulsant drug. Clonazepam brings about direct inhibition of cortical and sub-cortical epileptogenic focus and thus prevents the formation of convulsive activity. It displays several pharmacological properties, which are characteristics of benzodiazepine class of drugs. At the spinal cord level clonazepam depresses more reflex pathways and potentiates presynaptic inhibition of GABA in the CNS. Overcompensatory excitation processes are thereby reduced via negative feedback without substantiation of other physiologic neuronal activity.

Indications:

1. Epilepsy: Status epilepticus, Lennox - Gastaut syndrome, Infantile spasm, Absences seizure, Myoclonic seizure, Tonic - clonic seizure, Akinetic and atonic seizure & Partial seizure 2. Drug induced dyskinesias 3. Fulgurant pain 4. Bipolar affective disorder 5. Choreiform movements 6. Panic attacks

Dosage and administration:

The standard dose of clonazepam must be individually adjusted according to the patient's clinical response and tolerance of the drug. As a general rule, clonazepam is started with low single dose in a new patient.

Adults: 1 mg (elderly, 0.5 mg), initially at night for 4 nights, increased according to response over 2-4 weeks to usual maintenance dose of 4-8 mg which is usually given at night as a single dose or may be given in 3-4 divided doses if necessary.

Children: Up to 1 year, initially 0.25 mg, increased as above to usual maintenance dose of 0.5-1 mg, 1-5 years: initially 0.25 mg, increased as above to 1-3 mg, 5-12 years: initially 0.5 mg, increased as above to 3-6 mg.

Use in pregnancy and lactation:

The use of clonazepam during pregnancy or lactation should be avoided. The drug should only be administered to pregnant woman if the potential benefits of the patient outweigh the risk of fetus. Nursing mother must stop breast-feeding while taking clonazepam or vice versa.

Contraindications:

Clonazepam must not be used in patients with known hypersensitivity to any components of this preparation, in patients dependent on medications, drugs of abuse or alcohol, or suffering from myasthenia gravis.

Side effects:

Side effects like tiredness, sleepiness, muscular hypotonia, dizziness, co-ordination disturbance, hypersalivation in infants, paradoxical aggression, irritability, light-headache and ataxia may occur. These effects are usually transients and generally disappear spontaneously in the course of treatment or on the reduction of dosage.

Precautions:

The dosages of Clonazepam must be carefully adjusted to individual requirements in elderly patients, patients with pre-existing diseases of liver, kidney & respiratory system (e.g. chronic obstructive pulmonary disease) or undergoing treatment with other centrally acting medications. Special care should be taken while administering clonazepam in patients with spinal or cerebellar ataxia and in the event of acute intoxication with other centrally acting medications and analgesics.

Drug interactions:

Narcotics, barbiturates, non-barbiturates, hypnotics, anti-anxiety agents, MAO inhibitors, tricyclic antidepressant and anticonvulsant drugs may potentiate the CNS-depressant action of clonazepam.

Storage:

- Store below 30°C, keep in dry place & protect from light.
- Keep out of the reach of children.

Packing:

Arotril® 0.5 mg Tablet: Each box contains 100 tablets in blister pack.

Arotril® 1 mg Tablet: Each box contains 50 tablets in blister pack.

Arotril® 2 mg Tablet: Each box contains 30 tablets in blister pack.

Manufactured by:
 **ARISTOPHARMA LTD.**
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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