Clonil™

Clonazepam USP

Jenphar Bangladesh | جنفار بنغلاديش

Composition:
Clonil™ 0.5 Tablet: Each tablet contains Clonazepam USP 0.5 mg.
Clonil™ 2 Tablet: Each tablet contains Clonazepam USP 2 mg.

Pharmacology:
Clonazepam has pharmacological properties characteristic of the benzodiazepine class of drugs. It has sedative, hypnotic and anticonvulsant properties. Its basic anticonvulsive properties are also similar to those of other benzodiazepines.

Indication:
Clonazepam is indicated in most forms of epilepsy especially absence seizures including atypical absence seizures, Lennox-Gastaut syndrome, myoclonic and atonic seizures. For infantile spasms (including West-Syndrome) and tonic seizures it is only indicated as an adjunct or in refractory cases. Clonazepam is also indicated for the treatment of panic disorders, with or without agoraphobia.

Dose and administration:
Standard dosage: The dosage of Clonazepam must be individually adjusted according to the patient's clinical response and tolerance of the drug. As a general rule, Clonazepam is given as low-dose, single-drug therapy in new, non-therapy resistant cases.

Oral treatment in Epilepsy: To avoid adverse reactions at the beginning of therapy, it is essential to increase the daily dose progressively until the maintenance dose suited to the individual patient has been reached. The initial dose for infants and children up to the age of ten years (or up to 30 kg bodyweight) is 0.01-0.03 mg/kg daily. The daily maximum dose in children is 0.2 mg/kg of bodyweight and should not be exceeded. For children between 10 and 16 years, the initial dose is 1 to 1.5 mg/day given in 2 to 3 divided doses. The dose may be increased by 0.25 to 0.5 mg every third day until the maintenance dose (usually 3-6 mg/day) is reached. The initial dose for adults should not exceed 1.5 mg/day divided into 3 doses. The dose may be increased in increments of 0.5 mg every 3 days until the seizures are adequately controlled or limited by side effects. The maximum therapeutic dose for adults is 20 mg daily and should not be exceeded.

In panic disorder: The initial dose for adults with panic disorder is 0.25 mg twice daily (0.5 mg/day). An increase to 0.5 mg twice daily (1 mg/day) may be made after 3 days. Subsequent up-titration should be made at intervals of 3 days until panic disorder is controlled or limited by side effects. The usual maintenance dose is 1 mg twice daily (2 mg/day). A maximum dose of 2 mg twice daily (4 mg/day) may be prescribed in exceptional cases. Once a stable dose is reached, patients maybe switch to a once daily dose usually at bed time.

Duration: Maintenance treatment is recommended for at least 12-24 months, and in some cases, indefinitely. After at least 1 year of response, gradual discontinuation should be attempted with down-titration of 0.25 mg every 3 days until the drug is completely withdrawn and close follow-up of the patient. Relapsing patients should begin taking medication again.

Pediatric Patients: There is no clinical trial experience with Clonazepam in panic disorder in children.

OR AS DIRECTED BY THE PHYSICIAN.

Contra-indication:
Clonazepam is contraindicated in patients who are hypersensitive to Clonazepam or other benzodiazepines. It is also contraindicated in patients with severe respiratory insufficiency, severe hepatic impairment, sleep apnea syndrome, myasthenia gravis and narrow angle glaucoma.

Warning & precaution:
Benzodiazepines can produce severe withdrawal symptoms. Abrupt discontinuation or rapid dose reduction should be avoided. Special caution should be exercised in patients with mild to moderate hepatic impairment. Respiratory depression may occur following administration of Clonazepam. This effect may be aggravated by pre-existing airway obstruction or brain damage or if other medications which depress respiration have been given. Patients with a history of depression and/or suicide attempts should be kept under close supervision. Caution should be exercised while engaging in hazardous occupations requiring complete mental alertness, such as operating machinery or driving a motor vehicle. Clonazepam should be used with extreme caution in patients with a history of alcohol or drug abuse. The safety and efficacy of Clonazepam in patients with renal impairment has not been studied.

Side effects:
Common side effects of Clonazepam include somnolence, headache, upper respiratory tract infection, fatigue, dizziness, nausea, sinusitis, loss of balance and co-ordination & irritability. In infants, hypersalivation may occur.

Use in pregnancy & lactation:
Pregnancy: Safety of Clonazepam in pregnancy has not been established. Administration of high doses in the last trimester may cause irregularity in heartbeat of the unborn child, hypotonia, hyperthermia, mild respiratory depression and poor feeding in the neonate. The drug should only be administered to pregnant women only if there is a compelling indication and if the potential benefits outweigh the risk to the fetus.

Lactation: Mothers undergoing treatment with Clonazepam should not breastfeed. If there is a compelling indication for Clonazepam, breastfeeding should be discontinued.

Drug interaction:
Concurrent administrations of hepatic enzyme inducers such as Carbamazepine, Phenobarbitone or Phenytoin may accelerate the metabolism of Clonazepam. Concomitant intake of alcohol may effect the response to Clonazepam. It may be expected to have the sedative interaction associated with benzodiazepines in general.

Storage:
Store in a cool & dry place below 30^0 C, protect from light & moisture. Keep out of the reach of children.

Packing:
Clonil™ 0.5 Tablet: Each box contains 50 (5x10's) tablets in Alu-PVC blister packs.
Clonil™ 2 Tablet: Each box contains 50 (5x10's) tablets in Alu-PVC blister packs.

TM = Trade Mark

Manufactured by:
Jenphar Bangladesh Ltd.
Sreepur, Gazipur, Bangladesh

12002178 Ver.: 02