Cloron®

Clonazepam USP tablet

DESCRIPTION

Cloron® is the preparation of Clonazepam. It is a centrally acting muscle relaxant which has both anticonvulsant and antiepileptic effect. It is a benzodiazepine derivative, which binds to "benzodiazepine receptors" in various regions of the brain, including the brain stem, cerebellum, limbic system, and cerebral cortex. The precise mechanism by which Clonazepam exerts its antiseizure and antipanic effects is unknown, although it 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. Clonazepam is capable of suppressing the spike and wave discharge in absence seizures (petit mal) and decreasing the frequency, amplitude, duration, and spread of discharge in minor motor seizures.

INDICATIONS

Cloron® is indicated for

- All forms of epilepsy, myoclonus & status epilepticus
- Panic disorder

DOSAGE AND ADMINISTRATIONS

Dose of **Cloron®** is essentially individual and depends on all of the age of the patient. It will be determined in each patient according to clinical response and tolerance. In order to avoid initial side effects, it is essential to increase the daily dose progressively until the maintenance dose suited to the individual patient has been reached.

Seizure Disorder

Adults : Initial dose should not exceed 0.5 mg three times daily. Doses may be increased in increments of 0.5 to 1 mg every three days until seizure is adequately controlled or until side effects prevent any further increase.

Maintenance dosage must be individualized for each patient depending upon response.

Maximum recommended daily dose is 20 mg.

Paediatric : Dosage for initiation of therapy

Infants : 0.3 mg/day (one quarter of a 0.5 mg tablet in morning, half of a 0.5 mg tablet in the evening).

Children: 2 to 5 years : 0.5 mg/day (half of a 0.5 mg tablet morning and evening);

6 to 12 years : 0.75 mg/day (half of a 0.5 mg tablet in the morning, one 0.5 mg tablet in the evening)

Average dosage range for maintenance therapy:

Age	Daily dose	0.5 mg tablet	1 mg tablet	2 mg tablet
Infants (up to 2 years)	0.5 - 1 mg	1 - 2	½ - 1	¼ - ½
Small children (2 - 5 years)	1.5 - 3 mg	3 - 6	1 ½ - 3	¾ - 1 ½
School children (6 -12 years)	3 - 6 mg	6 - 12	3 - 6	1 ½ - 3
Adults	4 - 8 mg	8 - 16	4 - 8	2 - 4

*Maximum therapeutic dose is 20 mg/day

The daily quota should, if possible, be divided into three or four doses spread over the day. The maintenance dose should be attained after 2 to 4 weeks of treatment. To obtain minimum adjustment of the dose in infants and children, use of the 0.5 mg tablet is recommended. The double scored tablets facilitate administration of low doses in the early phase of treatment.

Panic Disorder

Adults : Initially 0.25 mg twice daily. Increased to 1 mg /day in two divided doses after 3 days.

Maximum dose : 4 mg /day in two divided doses.

Paediatric : No clinical trial under 18 years of age.

OVERDOSAGE

Symptoms of clonazepam overdosage, like those produced by other CNS depressants, include somnolence, confusion, coma and diminished reflexes. Treatment includes monitoring of respiration, pulse and blood pressure, general supportive measures and immediate gastric lavage. Intravenous fluids should be administered and an adequate airway should be maintained. Hypotension may be combated by the use of levarterenol or metaraminol. Methylphenidate or caffeine and sodium benzoate may be given to combat CNS depression.

CONTRAINDICATIONS

- Patients with known hypersensitivity to benzodiazepines
- Significant liver disease
- Respiratory depression
- Acute pulmonary insufficiency
- Acute narrow angle glaucoma
- Myasthenia gravis

PRECAUTIONS

Clonazepam should be used with caution in patients with chronic pulmonary insufficiency or with impairment of renal or hepatic function, and in the elderly or debilitated. In these cases, dosage may need to be reduced. Since alcohol can provoke epileptic seizures, irrespective of therapy, patients should be advised not to drink alcohol while under treatment. In combination with clonazepam, alcohol may modify the effects of the drug, compromise the success of therapy or give rise to unpredictable side effects. Drowsiness may affect performance of skilled tasks (e.g. driving).

SIDE-EFFECTS

Drowsiness, fatigue, dizziness, muscle hypotonia, coordination disturbances; hypersalivation in infants, paradoxical aggression, irritability and mental changes; rarely, blood disorders, abnormal liver-function test.

DRUG INTERACTIONS

Concomitant administration of hepatic enzyme inducers such as carbamazepine, phenobarbitone or phenytoin, may accelerate the metabolism of clonazepam. Clonazepam may be expected to have the sedative interactions associated with benzodiazepines in general.

USE IN PREGNANCY AND LACTATION

Pregnant women: Safety of Clonazepam in pregnancy has not been established. Use of Clonazepam during pregnancy should be avoided, as administration of high doses or prolonged use of low doses have been reported to produce irregularities in the fetal heart, hypotonia and poor sucking and hypothermia in the neonate.

Lactating mother: Clonazepam is excreted into the breast milk and can reach concentrations causing adverse effects and should therefore be avoided during breast-feeding.

PHARMACEUTICAL PRECAUTIONS

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Cloron® 0.5 mg tablet : Box containing 10 strips of 10 tablets each. Each tablet contains Clonazepam USP 0.5 mg.

Cloron® 2 mg tablet : Box containing 5 strips of 10 tablets each. Each tablet contains Clonazepam USP 2 mg.

SK+F
Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
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