

Cozepam[®] (Tablets)

Diazepam
Anticonvulsant

COZEPAM[®] 5MG TABLETS

PRESENTATION:

Cozepam[®] 5mg Tablets: Yellow, circular, flat, bevelled-edge tablet, embossed 'C' on one side and a breakline on the other side. Each tablet contains: Diazepam 5mg, Lactose and other excipients.

CLINICAL PHARMACOLOGY:

Diazepam is a long-acting benzodiazepine with anticonvulsant, anxiolytic, sedative, muscle relaxant and amnesic properties. Formation of the active metabolite, desmethyldiazepam, results in a long duration of action. The effects of Diazepam are mediated by enhancement of the activity of gamma-aminobutyric acid (GABA), a major inhibitory neurotransmitter in the brain. It appears to act at the limbic, thalamic, and hypothalamic levels of the Central Nervous System producing anxiolytic, sedative, hypnotic, skeletal muscle relaxant and anticonvulsant effects. Diazepam may inhibit monosynaptic and polysynaptic reflexes by acting as an inhibitory neuronal transmitter or by blocking excitatory synaptic transmission. It may also directly depress motor nerve and muscle function.

Pharmacokinetics:

Diazepam is readily and completely absorbed from the gastro-intestinal tract, peak plasma concentrations occurring within about 30 to 90 minutes of oral administration. Diazepam is highly lipid soluble and crosses the blood-brain barrier. Diazepam has a biphasic half-life with an initial rapid distribution phase followed by a prolonged terminal elimination phase of 1 to 2 days; its action is further prolonged by the even longer half-life of 2 to 5 days of its principal active metabolite. Diazepam is extensively bound to plasma proteins (98 to 99%). The plasma half-life of Diazepam is prolonged in neonates, in the elderly, and in patients with hepatic or renal impairment. Its metabolites cross the placental barrier and are distributed into breast milk.

USES:

Diazepam is used in the short term treatment of severe anxiety disorders, as a hypnotic in the short-term management of insomnia, as a sedative and premedicant, as an anticonvulsant (particularly in the management of status epilepticus and febrile convulsions), in the control of muscle spasm and in the management of alcohol withdrawal symptoms.

DOSAGE AND ADMINISTRATION:

Adults: Severe anxiety: 2mg 3 times daily to a maximum dose of 30mg a day split into several doses.

Insomnia associated with anxiety: 5 to 15mg at bedtime.

Seizures: 2mg-60mg each day in divided doses.

Muscle spasm: 2-15mg a day split into several doses.

Alcohol Withdrawal Syndrome: 5 to 20mg repeated if required after 2 to 4 hours.

Children (6 months of age and older): Muscle spasms in cerebral spasticity.

The maximum dose is 40mg a day split into several doses.



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Children (under 6 months of age): The child's doctor will decide how much should be given and how often.
Elderly and people with liver problems: As prescribed by the physician. The dose will be lower than the normal dose prescribed for other adults.

CONTRA-INDICATIONS AND WARNINGS:

Precautions:

Diazepam should be avoided in patients with pre-existing CNS depression or coma, respiratory depression, acute pulmonary insufficiency, myasthenia gravis, or sleep apnoea, and used with care in those with chronic pulmonary insufficiency. Diazepam should be given with care to elderly or debilitated patients who may be more prone to adverse effects. The sedative effects of diazepam are most marked during the first few days of use; affected patients should not drive or operate machinery. Diazepam is not appropriate for the treatment of chronic psychosis or for phobic or obsessional states. Dependence characterised by a withdrawal syndrome may develop after regular use of diazepam, even in therapeutic doses for short periods because of the risk of dependence. Diazepam should be used with caution in patients with a history of alcohol or drug abuse.

Adverse Effects:

Drowsiness, sedation, muscle weakness and ataxia are the most frequent adverse effects. Less frequent effects include vertigo, headache, confusion, mental depression, slurred speech or dysarthria, changes in libido, tremor, visual disturbances, urinary retention or incontinence, gastro-intestinal disturbances, changes in salivation, and amnesia. Jaundice, blood disorders and hypersensitivity reactions have been reported rarely. Treatment is generally symptomatic.

Interactions:

Enhanced sedation or respiratory and cardiovascular depression may occur if diazepam or other benzodiazepines are given with other drugs that have CNS depressant properties; these include alcohol, antidepressants, sedative antihistamines, antipsychotics, general anaesthetics, other hypnotics or sedatives, and opioid analgesics. The sedative effect of benzodiazepines may also be enhanced by cisapride.

PHARMACEUTICAL PRECAUTIONS:

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

LEGAL CATEGORY:

Prescription Only Medicine (POM)

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