

CALM-5 Tablets

(Diazepam Tablets)

COMPOSITION:

Calm-5 Tablets; Each tablet contains Diazepam BP 5mg.

PROPERTIES, ACTION AND FATE:

Calm-5 Tablets contain Diazepam, a benzodiazepine with anticonvulsant, anxiolytic, sedative, muscle relaxant and amnesic properties. Its actions are mediated by enhancement of the activity of aminobutyric acid (GABA), a major inhibitory neurotransmitter in the brain.

On oral administration, Diazepam is readily and completely absorbed from the gastrointestinal tract, peak plasma concentration occurring within about 30 to 90 minutes. It has a biphasic half-life with an initial rapid distribution phase followed by a prolonged terminal elimination phase of 1 or 2 days, its action is further prolonged by the even longer half-life of 2 to 5 days of its principal active metabolite, desmethyldiazepam.

Diazepam is extensively metabolised in the liver and is excreted in the urine, mainly in the form of its metabolites, either free or in conjugated form.

INDICATIONS:

Calm-5 Tablets are used in the treatment of severe anxiety disorders, as 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 as in tetanus, and in the management of alcohol withdrawal symptoms.

DOSAGE AND ADMINISTRATION:

Calm-5 Tablets are administered by the oral route. In view of the risk of dependence, diazepam should always be given in the lowest dose which can control symptoms and in short courses, treatment should not normally continue beyond 4 weeks and should always be withdrawn gradually. Intermittent treatment regimens may decrease the risk of dependence.

Dosage:

Diagnosis	Dose
Anxiety disorders	2mg three times daily, increased up to 30mg daily in divided doses.
Insomnia associated with anxiety	A single dose of 5mg to 30mg before retiring to bed.
Muscle spasm	2mg to 15mg daily in divided doses increased in severe spastic disorders, such as cerebral palsy. As an adjunctive in some types of epilepsy upto 60mg daily in divided doses.
Management of mild to moderate symptoms of alcohol withdrawal	5-20mg, repeated if necessary in 2 to 4 hours, or 10mg 3 to 4 times on the first day reducing to 5mg 3 to 4 times daily as required
For premedication before dental or minor surgical procedures	A single dose of 5mg to 20mg.

Children: The recommended initial dose of diazepam for children is 0.1mg to 0.2mg per Kg body-weight orally but up to 0.8mg per Kg body weight daily has been given.

Dosage recommendation of diazepam for premature infants is not generally given since they may be unable to metabolise the drug.

PRECAUTIONS, WARNINGS AND ADVERSE-EFFECTS:

- Calm-5 Tablets** should be avoided in patients with pre-existing CNS depression or coma, acute pulmonary insufficiency, or sleep apnoea, and used with caution in those with chronic pulmonary insufficiency, impaired hepatic or renal function, and in elderly or debilitated patients.
- Calm-5 Tablets** are contraindicated in patients with known hypersensitivity to diazepam or other benzodiazepines, and in those with chronic psychosis or phobic or obsessional states.
- The preparation is not recommended for use in pregnant patients during the first trimester or late pregnancy.
- Drug dependence may develop after regular use of diazepam or other benzodiazepines, even in therapeutic doses for short periods.
- The most frequent adverse effects occasionally associated with diazepam therapy include, drowsiness, sedation and ataxia, and other less frequent effects include vertigo, headache, confusion, mental depression, slurred speech or dysarthria, changes in libido, tremor, visual disturbances, urinary incontinence, gastrointestinal disturbances and hypersensitivity reactions.
- It is recommended that withdrawal of diazepam therapy should be gradual as abrupt withdrawal may result in confusion, toxic psychosis, convulsions or a condition resembling delirium tremens.

LEGAL CATEGORY: Prescription Only Medicine (POM).

THERAPEUTIC CATEGORY: ATC: N04C (Hypnotic – sedative).

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

SHELF LIFE: As per the product label.

PRESENTATION: **Calm-5 Tablets** in packs of 10 x 10's and 1000's.

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LICENCE HOLDER: LABORATORY & ALLIED LTD.



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