

Dormitol™

Midazolam BP

COMPOSITION

Dormitol™ 7.5 tablet: Each film coated tablet contains Midazolam BP 7.5 mg as Midazolam Maleate.

Dormitol™ 15 tablet: Each film coated tablet contains Midazolam BP 15 mg as Midazolam Maleate.

Dormitol™ injection: Each 3 ml injection contains Midazolam BP 15 mg as Midazolam Hydrochloride.

PHARMACOLOGY

Midazolam is a benzodiazepine derivative which has a rapid onset and short duration of action. It is a sleep inducing agent and used as premedicant in surgical and diagnostic procedures as well as for anaesthesia. It has also anxiolytic, anticonvulsant and muscle relaxant properties.

INDICATION

Dormitol™ is used as:-

- Hypnotic and hence it is used for short term management of insomnia
- Sedative and hence it relieves anxiety, tension and fear
- Pre-anaesthetics and
- Anticonvulsants

DOSAGE & ADMINISTRATION

Treatment should be as short as possible. The duration of treatment with **Dormitol™** should not be more than of 2 weeks. The tapering-off process should be tailored to the individual. In certain cases extension beyond the maximum treatment period may be necessary. But it should not take place without reevaluation of the patient's status.

Dormitol™ tablets should be taken immediately before going to bed and swallowed whole with fluid to get the rapid onset of action. Treatment should be started with the lowest recommended dose. The maximum dose should not be exceeded because of the increased risk of CNS adverse effects.

Adults: - 7.5 mg to 15 mg daily,

Elderly: - 7.5 mg daily.

Premedication: 7.5 mg to 15 mg, should be given 30-60 minutes before the procedure.

Special dosage instructions: In patients with impaired liver function, the recommended dose is 7.5 mg.

CONTRAINDICATION

Known hypersensitivity to Midazolam or other benzodiazepines, severe respiratory insufficiency, severe hepatic insufficiency, sleep apnea syndrome, myasthenia gravis, patients with a history of alcohol or drug abuse and for the children, Midazolam is contraindicated.

PRECAUTIONS

CNS depressants, Erythromycin,azole type antimycotics and Cimetidine may interfere the metabolism of Midazolam. So caution should be taken during the concomitant treatment with these drugs along with Midazolam. Long term use of Midazolam may increase dependency. As Midazolam is a strong sedative, it should not be taken before driving or other performance skilled tasks.

PREGNANCY AND LACTATION

Insufficient data are available on Midazolam to assess its safety during pregnancy. But benzodiazepines adversely affect the human fetus. So their use should be avoided if there is safer alternative. Midazolam is excreted through breast milk. Therefore, Midazolam should not be used by the nursing mothers.

SIDE EFFECTS

Drowsiness is the most common side effect. Less common side effects are CNS depression, ataxia, confusion, tiredness, muscle weakness, fatigue, headache, dizziness and double vision. These effects occur predominantly at the start of treatment and usually disappear with dose adjustment or continuation of therapy.

DRUG INTERACTION

CNS depressants, Erythromycin,azole type antimycotics and Cimetidine may interact with Midazolam.

OVERDOSAGE

Midazolam should not be used more than the dosage guideline. Over dose produces severe depression ranging from drowsiness to coma.

STORAGE

Protect from light & moisture, store in cool and dry place. Keep out of reach of children.

HOW SUPPLIED

Dormitol™ 7.5 tablet: Each box contains 30 tablets in blister pack.

Dormitol™ 15 tablet: Each box contains 20 tablets in blister pack.

Dormitol™ 15 mg/3 ml injection: Each box contains 1 ampoule of 3 ml.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
Pabna, Bangladesh

TM-Trade Mark.