

Dormitol[®]

Midazolam BP

COMPOSITION

Dormitol[®] 7.5 tablet: Each film coated tablet contains Midazolam BP 7.5 mg

Dormitol[®] Injection: Each 3 ml injection contains Midazolam BP 15 mg

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

Midazolam 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

Anticonvulsants

DOSAGE & ADMINISTRATION

The duration of treatment with oral midazolam should not be more than of 2 weeks. In certain cases extension beyond the maximum treatment period may be necessary.

Insomnia: 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

Endoscopic or Cardiovascular procedures:

Adult: initial dose is 2.5 mg (IV)

Elderly & debilitated patients: 1-1.5 mg (IV)

Induction of Anesthesia: Adult: 10-15 mg (IV) or 0.07-0.1 mg/Kg body weight, usually 5 mg (IM)

Children: 0.15-0.20 mg/Kg (IM)

Elderly & debilitated patients: 0.025-0.05 mg/Kg (IM)

Rectal administration in children: for preoperative sedation, rectal administration of the ampoule solution is 0.35-0.45 mg/Kg, 20-30 min before induction of general anesthesia

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 children.

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 time 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 dosage produces severe depression ranging from drowsiness to coma.

STORAGE

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

HOW SUPPLIED

Dormitol[®] 7.5 tablet: Each box contains 30 tablets in blister pack

Dormitol[®] Injection: Each box contains 1 ampoule of 3 ml

Manufactured by :



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