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 animycotics 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 animycotics and cimetidine may interact
with Midazolam.

OVERDOSE
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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