



Hypnofast[®]

Midazolam

Presentation

Hypnofast[®] 7.5 tablet: Each tablet contains Midazolam BP 7.5 mg (as Midazolam Maleate).

Hypnofast[®] 15 tablet: Each tablet contains Midazolam BP 15 mg (as Midazolam Maleate).

Hypnofast[®] 15 mg/3 ml Injection: Each 3 ml ampoule contains Midazolam BP 15 mg (as Midazolam Hydrochloride).

Hypnofast[®] 5 mg/5 ml Injection: Each 5 ml ampoule contains Midazolam BP 5 mg (as Midazolam Hydrochloride).

Description

Midazolam is a sleep inducing agent characterized by a rapid onset and short duration of action. It also exerts an anxiolytic, anticonvulsant and muscle-relaxant effect.

Indications & Uses

- Short-term treatment of insomnia.
- Sedation in premedication before surgical or diagnostic procedures.

Dosage & Administration

Oral dosage: For adults 7.5-15 mg daily. In elderly and debilitated patients, the recommended dose is 7.5 mg. In premedication, 15 mg of Midazolam should be given 30-60 minutes before the procedure.

Intravenous administration:

- Endoscopic or Cardiovascular Procedures

In healthy adults the initial dose is approximately 2.5 mg. In cases of severe illness and in elderly patients, the initial dose must be reduced to 1 to 1.5 mg.

- Induction of Anesthesia

The dose is 10-15 mg I. V.

Intramuscular administration:

Adult: 0.07-0.1 mg/kg body weight i. m. Usual dose is about 5 mg

Children: 0.15-0.20 mg/kg

Elderly and debilitated patients: 0.025-0.05 mg/kg

Rectal administration in children:

For preoperative sedation, rectal administration of the ampoule solution (0.35-0.45 mg/kg) 20-30 min. before induction of general anesthesia.

Side-effects

At the start of therapy, drowsiness during daytime, confusion, fatigue, headache and muscle weakness may occur which usually disappear with repeated administration. Following parenteral (IV or IM) administration of Midazolam, fluctuations in vital signs have been noted including respiratory depression, apnea, variations in blood pressure and pulse rate.

Precaution

Midazolam IV should be administered very slowly.

Pregnancy and Lactation

Midazolam should be avoided during pregnancy unless there is no safer alternative. Since Midazolam passes into breast milk, it should not be administered to breast-feeding mothers.

Contraindications

Midazolam must not given to patients with severe respiratory insufficiency, severe hepatic insufficiency, myasthenia gravis, sleep apnea syndrome and with known hypersensitivity to benzodiazepines or to any component of the product.

Drug Interaction

Midazolam can enhance the central sedative effect of neuroleptics, tranquilizers, antidepressants, sleep-inducing drugs, analgesics, anaesthetics, antipsychotics, anxiolytics, antiepileptic drugs and sedative antihistamines.

Overdosage

Extreme overdosage may lead to coma, areflexia, cardiorespiratory depression and apnea. The effects of overdosage can be controlled with benzodiazepine antagonist flumazenil.

Commercial pack

Hypnofast[®] 7.5 tablet: Each box contains 3 blister strips of 10 tablets.

Hypnofast[®] 15 tablet: Each box contains 3 blister strip of 10 tablets.

Hypnofast[®] 15 mg/3 ml Injection: Each box contains 1 ampoule of 3 ml.

Hypnofast[®] 5 mg/5 ml Injection: Each box contains 1 ampoule of 5 ml.

Manufactured by
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