

Only for the use of Medical Professionals

Dormilat[®]

Midazolam Hydrochloride

Description

Dormilat[®] is a preparation of Midazolam Hydrochloride which is a benzodiazepine derivative. It has a rapid onset and short duration of action. Midazolam is mediated through the inhibitory neurotransmitter gamma-aminobutyric acid (GABA), that is one of the major inhibitory neurotransmitters in the brain. Benzodiazepines increase the activity of GABA, thereby producing a calming effect, relaxing skeletal muscles, and inducing sleep.

Indications and usage

Dormilat[®] is used as

- Short-term management of insomnia
- Sedation in premedication before surgery or during diagnostic, therapeutic or endoscopic procedures
- Long-term sedation in intensive care units

Dosage and administration

Duration of treatment should be as short as possible. Generally the duration of treatment should not be more than of 2 weeks. In certain cases extension beyond the maximum treatment period may be necessary.

Dormilat[®] Tablet:

Adults:

Insomnia: Standard dosage is 7.5 mg to 15 mg daily, in elderly 7.5 mg daily.

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

Dormilat[®] Injection:

Adults:

Preoperative sedation: 0.07 to 0.1mg/kg (usual dose 5 mg) IM given 30 to 60 minutes preoperative.

Conscious sedation:

- **IV direct:** 1 to 2.5mg (0.015 to 0.035 mg/kg) IV direct over 2 minutes; after an additional 2 minute period, may repeat in small increments, waiting at least 2 minutes between increments, until desired effect, to a maximum of 0.1 mg/kg.
- **Elderly or debilitated:** IV direct: decrease initial dose to 1-1.5 mg IV to a maximum of 0.07 mg/kg
- **IV infusion:** loading dose of 2 to 2.5 mg IV direct (0.03 mg/kg) followed by 2 mg/hr infusion (0.01 to 0.03 mg/kg/hour). Adjust for adequate sedation, increasing by increments of 25 to 50% of the initial dose at 30 minute intervals
- **IM/SC:** 1 to 5mg IM/SC repeated every 2 to 4 hours as necessary

Induction of anesthesia: 0.30-0.35 mg/kg IV direct. In elderly or debilitated; decrease initial dose to 0.2-0.3 mg/kg IV

Terminal agitation in the palliative patient: 2.5-10 mg IV/SC, followed by IV/SC infusion of 30-240 mg/24 hrs; titrate, increasing by increments of 25-50% of the initial rate at 30 minute intervals and according to goals of care

Children:

IV direct: 0.1 mg/kg IV over 2-3 minutes; may repeat dose at 5 minute intervals; maximum total dose is 8mg.

Oral: 0.5-0.75 mg/kg as a pre-anaesthetic; draw dose from ampoule and mix with juice prior to administration

Use in pregnancy and lactation

Midazolam is pregnancy category D. 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, euphoria, hallucinations, and double vision. These effects occur predominantly at the start of treatment and usually disappear with dose adjustment or continuation of therapy.

Precautions

Caution should be exercised when administering Midazolam parenterally to patients with Cardiac disease; respiratory disease; myasthenia gravis; neonates; children (particularly if cardiovascular impairment); risk of airways obstruction and hypoventilation in children under 6 months (monitor respiratory rate and oxygen saturation); history of drug or alcohol abuse; reduce dose in elderly and debilitated; risk of severe hypotension in hypovolaemia, vasoconstriction, hypothermia; avoid prolonged use (and abrupt withdrawal thereafter). Dosage adjustments are necessary in the presence of renal or hepatic dysfunction. As Midazolam is a strong sedative, it should not be taken before driving or other performance skilled tasks.

Contraindications

Midazolam is contraindicated in patients with known hypersensitivity to Midazolam or other benzodiazepines or to any component of the product.

Drug interaction

HIV protease inhibitors, nefazodone, sertraline, grapefruit juice, fluoxetine, erythromycin, diltiazem, clarithromycin inhibit the metabolism of Midazolam. St John's wort, rifampine, rifampin, rifabutin, phenytoin enhance the metabolism of Midazolam leading to a reduced action. Sedating antidepressants, antiepileptic drugs such as phenobarbital, phenytoin and

carbamazepine, sedative antihistamines, opiates, antipsychotics and alcohol enhance the sedative effects of Midazolam.

Overdose

The manifestations of Midazolam overdose reported are similar to those observed with other benzodiazepines, including sedation, somnolence, confusion, impaired coordination, diminished reflexes, coma and untoward effects on vital signs. Flumazenil, a specific benzodiazepine-receptor antagonist, is indicated for the complete or partial reversal of the sedative effects of benzodiazepines

Pharmaceutical precautions

Store in a cool, dry place. Protect from light. Keep out reach of children

Presentation

Dormilat[®] 15mg injection: Each 3ml ampoule contains Midazolam 15mg as hydrochloride USP

Dormilat[®] 5mg injection: Each 5ml ampoule contains Midazolam 5mg as hydrochloride USP

Dormilat[®] 7.5mg tablet: Each tablet contains midazolam 7.5mg as maleate USP

Package quantities

Dormilat[®] 15mg injection : Carton of 1 ampoule per pack

Dormilat[®] 5mg injection : Carton of 1 ampoule per pack

Dormilat[®] 7.5mg tablet:

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