

PRESCRIBING INFORMATION

Hypozam Injection IM/IV

(Midazolam Injection USP)

هاپوزام انجکشن آئی ایم/آئی وی

COMPOSITION:

Each ml contains:
Midazolam (as HCl).....Brookes Specs..... 1.0 mg

DESCRIPTION:

Hypozam (Midazolam Injection USP) is a short acting benzodiazepine, used as a premedication and sedative in surgical procedures and for the induction of anaesthesia. Onset time of sedative effects after IM administration is 15 minutes with peak sedation occurring in 30-60 minutes. Sedation after IV injection is achieved within 3-5 minutes. When given intravenously as an anaesthetic induction agent, induction occurs in approximately 1.5 minutes with narcotic pre-medication and in 2 to 2.5 minutes without narcotic pre-medication.

Bio-availability is higher but variable after intramuscular administration. Midazolam is lipophilic at physiological pH. It crosses the placenta. Midazolam is extensively (about 96%) bound to plasma proteins. Midazolam usually has a short elimination half-life of about 2 hours although half-life longer than 7 hours have been reported in some patients. The half-life of Midazolam is prolonged in neonates, in the elderly, and in patients with liver disorders. Midazolam is metabolized in the liver, the major metabolite is 1-hydroxy methyl midazolam which is excreted through kidney.

INDICATIONS:

For induction of general anaesthesia.

For preoperative sedation (induction of sleepiness and relief of apprehension) and also to impair memory of preoperative events. In combination with nitrous oxide and oxygen (balanced anaesthesia) for short surgical procedures. As an agent for conscious sedation prior to diagnostic procedures e.g. bronchoscopy, gastroscopy, endoscopy, coronary angiography & cardiac catheterization.

DOSAGE AND ADMINISTRATION:

Hypozam (Midazolam Injection USP) is a potent sedative agent which requires slow IM or IV administration with provision for monitoring and equipment to counteract cardio-respiratory events. Hypozam injection can safely be mixed in conventional drips and infusion.

Induction of Anaesthesia:

Individual response to the drug is variable. The dosage should be titrated to the desired effects according to patient's age and clinical status.

Unpremedicated Patients:

Initial dose of 0.3 to 0.35 mg/kg of body weight for induction, administered over 20 to 30 seconds and allowing 2 minutes for effects.

Premedicated Patients:

When the patients have received sedative or narcotic pre-medication the range of recommended dose is 0.15 to 0.35 mg/Kg body weight. In average adults below 55 years, a dose of 0.25 mg/Kg of body weight administered over 20 to 30 seconds and allowing 2 minutes for effects.

Pre-operative sedation:

IM for pre-operative sedation (Induction of sleepiness, drowsiness, release of apprehension and to impair memory of pre-operative events). For pre-medication the recommended dose of Hypozam is 0.07 to 0.08 mg/Kg of body weight IM. For average adults, approximate dose is 5.0 mg IM one hour before surgery.

For conscious sedation:

Hypozam (Midazolam Injection USP) can be safely used for conscious sedation, dosage must be individualized and titrated. Individual response varies with age, physical status and concomitant medications. Initially 1 mg IV then increase the dose up to 2.5 mg over a period of 2 minutes and then evaluate the sedative effects and if not achieved continue to titrate slowly to the appropriate level of sedation.

For maintenance, add 25% of dose used to first reach the sedative end point.

CONTRAINDICATIONS:

Hypozam (Midazolam Injection USP) injection is contra-indicated in patients with known hypersensitivity to the drug. Benzodiazepines are contraindicated in patients with acute narrow angle glaucoma.

SIDE EFFECT:

Fluctuations in vital signs including decreased respiratory effects, variation in blood pressure and pulse rate are the most frequently seen findings.

Respiratory:

Laryngospasm, bronchospasm, dyspnoea, hyperventilation and airway obstruction.

Cardiovascular:

Premature ventricular contraction, vasovagal episode and tachycardia.

CNS/Neuromuscular:

Retrograde amnesia, euphoria, confusion, nervousness, restlessness, nightmares dysphonia and paresthesia.

Special senses:

Blurred vision, diplopia, nystagmus, visual disturbances, blocked ears, loss of balance and light headedness.

Others:

Headache, hiccough, nausea, vomiting, yawning, lethargy, weakness and faint feeling.

OVER DOSAGE:

Over dosage effects are expected to be similar to those observed with other benzodiazepines. No evidence of specific organ toxicity.

STORAGE:

Store at temperature 15-30 °C away from light.

PRESENTATION:

Pack of 10 x 3 ml ampoules.

Pack of 10 x 5 ml ampoules.

خوراک اور طریقہ استعمال:

ہائپو زیم انجکشن ایک خواب آور دوا ہے جو عضلاتی اور وریڈی انجکشن کے ذریعے آہستہ آہستہ دی جاتی ہے۔
ہائپو زیم انجکشن کو آپریشن سے پہلے اور بیہوشی کی ادویات (اینسٹھیسیا) کی ادویات کے ساتھ استعمال کیا جاتا ہے۔
ہائپو زیم انجکشن محفوظ طریقے سے روایتی (کنوینشنل) ڈرپس اور انفیوژن میں ملایا جاسکتا ہے۔

اسٹوریج:

15 سے 30 ڈگری سینٹی گریڈ درجہ حرارت پر روشنی سے بچا کر رکھیے۔

brookes

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