FRESENIUS KABI

Midazolam
Injection, USP

2 mg per 2 mL Simplist® ready-to-administer prefilled syringes +RFID® available from Fresenius Kabi.

- Manufacturer prepared
- Preservative free
- 36-month shelf life
- RFID-embedded
- Ready-to-read
- Clear and distinct labeling

Midazolam Injection, USP

INDICATIONS AND USAGE

Midazolam Injection, USP is indicated:

- intramuscularly or intravenously for preoperative sedation/anxiolysis/amnesia;
- intravenously as an agent for sedation/anxiolysis/amnesia prior to or during diagnostic, therapeutic or endoscopic procedures, such as bronchoscopy, gastroscopy, cystoscopy, coronary angiography, cardiac catheterization, oncology procedures, radiologic procedures, suture of lacerations and other procedures either alone or in combination with other CNS depressants;
- intravenously for induction of general anesthesia, before administration of other anesthetic agents. With the use of narcotic premedication, induction of anesthesia can be attained within a relatively narrow dose range and in a short period of time. Intravenous midazolam can also be used as a component of intravenous supplementation of nitrous oxide and oxygen (balanced anesthesia);
- continuous intravenous infusion for sedation of intubated and mechanically ventilated patients as a component of anesthesia or during treatment in a critical care setting.

IMPORTANT SAFETY INFORMATION:

WARNING

Personnel and Equipment for Monitoring and Resuscitation

Adults and Pediatrics: **Intravenous midazolam has been associated with respiratory depression and respiratory arrest, especially when used for sedation in noncritical care settings. In some cases, where this was not recognized promptly and treated effectively, death or hypoxic encephalopathy has resulted. Intravenous midazolam should be used only in hospital or ambulatory care settings, including physicians' and dental offices, that provide for continuous monitoring of respiratory and cardiac function, e.g., pulse oximetry. Immediate availability of resuscitative drugs and age- and size-appropriate equipment for bag/valve/mask ventilation and intubation, and personnel trained in their use and skilled in airway management should be assured. For deeply sedated pediatric patients, a dedicated individual, other than the practitioner performing the procedure, should monitor the patient throughout the procedure.**

Risks from Concomitant Use with Opioids

Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Monitor patients for respiratory depression and sedation.

Individualization of Dosage

Midazolam must never be used without individualization of dosage. The initial intravenous dose for sedation in adult patients may be as little as 1 mg, but should not exceed 2.5 mg in a normal healthy adult. Lower doses are necessary for older (over 60 years) or debilitated patients and in patients receiving concomitant narcotics or other central nervous system (CNS) depressants. The initial dose and all subsequent doses should always be titrated slowly; administer over at least 2 minutes and allow an additional 2 or more minutes to fully evaluate the sedative effect. The use of the 1 mg/mL formulation or dilution of the 1 mg/mL or 5 mg/mL formulation is recommended to facilitate slower injection. Doses of sedative medications in pediatric patients must be calculated on a mg/kg basis, and initial doses and all subsequent doses should always be titrated slowly. The initial pediatric dose of midazolam for sedation/anxiolysis/amnesia is age, procedure, and route dependent.

Neonates: **Midazolam should not be administered by rapid injection in the neonatal population. Severe hypotension and seizures have been reported following rapid IV administration, particularly with concomitant use of fentanyl.**

Contradictions: Injectable midazolam is contraindicated in patients with a known hypersensitivity to the drug. Benzodiazepines are contraindicated in patients with acute narrow-angle glaucoma. Benzodiazepines may be used in patients with open-angle glaucoma only if they are receiving appropriate therapy. Measurements of intraocular pressure in patients without eye disease show a moderate lowering following induction with midazolam; patients with glaucoma have not been studied.

Warnings and Precautions

Risk of Respiratory Adverse Events: Serious cardiorespiratory adverse events have occurred after administration of midazolam. These have included respiratory depression, airway obstruction, oxygen desaturation, apnea, respiratory arrest and/or cardiac arrest, sometimes resulting in death or permanent neurologic injury.

Other Adverse Events: Reactions such as agitation, involuntary movements (including tonic/clonic movements and muscle tremor), hyperactivity and combativeness have been reported in both adult and pediatric patients. These reactions may be due to inadequate or excessive dosing or improper administration of midazolam; however, consideration should be given to the possibility of cerebral hypoxia or true paradoxical reactions.

Concomitant Use of Central Nervous System Depressants: Concomitant use of barbiturates, alcohol or other central nervous system depressants may increase the risk of hypoventilation, airway obstruction, desaturation, or apnea and may contribute to profound and/or prolonged drug effect.

Debilitation and Comorbid Considerations: Higher risk adult and pediatric surgical patients, elderly patients and debilitated adult and pediatric patients require lower dosages, whether or not concomitant sedating medications have been administered. Adult or pediatric patients with COPD are unusually sensitive to the respiratory depressant effect of midazolam. Pediatric and adult patients undergoing procedures involving the upper airway are particularly vulnerable to episodes of desaturation and hypoventilation due to partial airway obstruction. Adult and pediatric patients with chronic renal failure and patients with congestive heart failure eliminate midazolam more slowly. Injectable midazolam should not be administered to adult or pediatric patients in shock or coma, or in acute alcohol intoxication with depression of vital signs. Particular care should be exercised in the use of intravenous midazolam in adult or pediatric patients with uncompensated acute illnesses, such as severe fluid or electrolyte disturbances.

Risk of Intra-arterial Injection: The safety and efficacy of midazolam following non-intravenous and non-intramuscular routes of administration have not been established. Midazolam should only be administered intramuscularly or intravenously.

Return to Full Cognitive Function: Midazolam is associated with a high incidence of partial or complete impairment of recall for the next several hours. It is recommended that no patient operate hazardous machinery or a motor vehicle until the effects of the drug, such as drowsiness, have subsided or until one full day after anesthesia and surgery, whichever is longer. For pediatric patients, particular care should be taken to assure safe ambulation.

Neonatal Sedation and Withdrawal Syndrome: Use of midazolam late in pregnancy can result in sedation (respiratory depression, lethargy, hypotonia) and/or withdrawal symptoms (hyperreflexia, irritability, restlessness, tremors, inconsolable crying, and feeding difficulties) in the neonate. Monitor neonates exposed to midazolam during pregnancy or labor for signs of sedation and monitor neonates exposed to midazolam during pregnancy for signs of withdrawal; manage these neonates accordingly.

Pediatric Neurotoxicity: Published animal studies demonstrate that the administration of anesthetic and sedation drugs that block NMDA receptors and/or potentiate GABA activity increase neuronal apoptosis in the developing brain and result in long-term cognitive deficits when used for longer than 3 hours. Decisions regarding the timing of any elective procedures requiring anesthesia should take into consideration the benefits of the procedure weighed against the potential risks.

Pregnancy: Advise pregnant females that use of midazolam late in pregnancy can result in sedation (respiratory depression, lethargy, hypotonia) and/or withdrawal symptoms (hyperreflexia, irritability, restlessness, tremors, inconsolable crying, and feeding difficulties) in newborns. Instruct patients to inform their healthcare provider if they are pregnant.

Nursing: Instruct patients to notify their healthcare provider if they are breastfeeding or intend to breastfeed. Instruct breastfeeding patients receiving midazolam to monitor infants for excessive sedation, poor feeding, and poor weight gain, and to seek medical attention if they notice these signs. Because of the potential for serious adverse reactions advise patients that breastfeeding is not recommended during treatment with midazolam. A lactating woman may consider pumping and discarding breastmilk for at least 4 to 8 hours after receiving midazolam for sedation or anesthesia to minimize drug exposure to a breastfed infant.

Adverse Reactions

Fluctuations in vital signs were the most frequently seen findings following parenteral administration of midazolam in adults and including decreased tidal volume, respiratory rate decrease (23.3% of patients following intravenous and 10.8% of patients following intramuscular administration), apnea (15.4% of patients following intravenous administration), as well as variations in blood pressure and pulse rate. The majority of serious adverse effects, particularly those associated with oxygenation and ventilation, have been reported when midazolam is administered with other medications capable of depressing the central nervous system. Additional Adverse Reactions: Adults: *Intramuscular Administration:* headache, injection site pain; *Intravenous Administration:* hiccoughs, nausea, vomiting, coughing, over sedation, headache, drowsiness, tenderness at injection site, pain at injection site, redness, induration. Pediatric: *Intravenous Administration:* desaturation, apnea, hypotension, paradoxical reactions, hiccough, seizure-like activity, and nystagmus.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC, at 1-800-551-7176 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

Overdosage: Overdosage of benzodiazepines is characterized by central nervous system depression ranging from drowsiness to coma. In severe overdosage cases, patients may develop respiratory depression and coma. Overdosage of benzodiazepines in combination with other CNS depressants (including alcohol and opioids) may be fatal. In managing benzodiazepine overdosage, employ general supportive measures, including intravenous fluids and airway maintenance. Flumazenil, a specific benzodiazepine receptor antagonist indicated for the complete or partial reversal of the sedative effects of benzodiazepines in the management of benzodiazepine overdosage, can lead to withdrawal and adverse reactions, including seizures, particularly in the context of mixed overdosage with drugs that increase seizure risk and in patients with long-term benzodiazepine use and physical dependency. The risk of withdrawal seizures with flumazenil use may be increased in patients with epilepsy. Flumazenil is contraindicated in patients who have received a benzodiazepine for control of a potentially life-threatening condition (e.g., status epilepticus). If the decision is made to use flumazenil, it should be used as an adjunct to, not as a substitute for, supportive management of benzodiazepine overdosage. See the flumazenil injection Prescribing Information.

This Important Safety Information does not include all the information needed to use MIDAZOLAM INJECTION, USP safely and effectively. Please see full prescribing information, including BOXED WARNING, for MIDAZOLAM INJECTION, USP at www.simplist-us.com.

Simplist®

Midazolam
Injection, USP

Strength	2 mg per 2 mL
Concentration	1 mg per mL
Fill volume	2 mL
Description	Single Dose Prefilled Syringe
Unit of sale NDC	76045-211-20
Unit of sale bar code	N(01)30376045211208
Pack size	24
Secondary packaging	Blister
Blister dimensions	5.748" x 1.063"
Carton dimensions	6.25" x 2.402" x 6.575"
Wholesale numbers	
Cardinal	5981956
Cencora	10299107
McKesson	3026358
Morris & Dickson	606467

To place an order, contact your Sales Representative or call Customer Service at 1.888.386.1300 | www.plusRFID.com

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