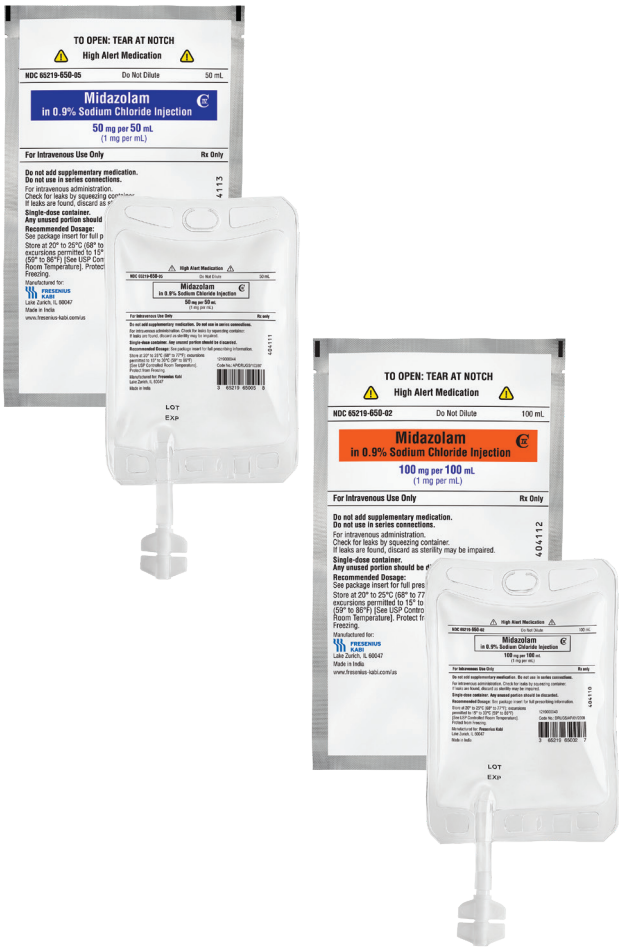
Midazolam

in 0.9% Sodium Chloride Injection

Fresenius Kabi offers a growing portfolio of premix medications in bags not made with PVC or DEHP. We are committed to bringing quality medicines and technologies to clinicians, when and where they need them most.



- Preservative-free
- Bar-coded
- Flexible bag container is not made with natural rubber latex
- Not made with PVC/DEHP

Fill Volume	50 mL	100 mL
Product Code	651050	651010
NDC	65219-650-50	65219-650-10
Strength	50 mg per 50 mL	100 mg per 100 mL
Concentration	1 mg per mL	1 mg per mL
Units/case	10	10
UPC	(01)30365219650509(21)123456789012	(01)30365219650103(21)123456789012
Wholesaler/Distributor Information		
Cardinal	5982483	5977277
Cencora	10299091	10298584
McKesson	3026747	3023256
Morris & Dickson	606459	594499

WARNING: PERSONNEL AND EQUIPMENT FOR MONITORING AND RESUSCITATION AND RISKS FROM CONCOMITANT USE WITH OPIOID ANALGESICS AND OTHER SEDATIVE-HYPNOTICS

Personnel and Equipment for Monitoring and Resuscitation

- **Only personnel trained in the administration of procedural sedation, and not involved in the conduct of the diagnostic or therapeutic procedure, should administer Midazolam in 0.9% Sodium Chloride Injection.**
- **Administering personnel must be trained in the detection and management of airway obstruction, hypoventilation, and apnea, including the maintenance of patent airway, supportive ventilation, and cardiovascular resuscitation.**
- **Resuscitative drugs, and age- and size-appropriate equipment for bag/valve/mask assisted ventilation must be immediately available during administration of Midazolam in 0.9% Sodium Chloride Injection.**
- **Continuously monitor vital signs during sedation and during the recovery period.**

Risks from Concomitant Use with Opioid Analgesics and Other Sedative Hypnotics

Concomitant use of benzodiazepines, including Midazolam in 0.9% Sodium Chloride Injection, and opioids may result in profound sedation, respiratory depression, coma, and death. Continuously monitor patients for respiratory depression and depth of sedation.

Please see Important Safety Information, including BOXED WARNING on the following page.

For more information or to place an order, contact your Sales Representative or call Customer Service at 1.888.386.1300 | freseniuskabipremixbags.com

FRESENIUS KABI

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Lake Zurich, IL 60047
Phone: 1.888.386.1300
www.fresenius-kabi.com/us

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IMPORTANT SAFETY INFORMATION

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CONTRAINDICATIONS

Midazolam in 0.9% Sodium Chloride Injection is contraindicated in patients with:
- Known hypersensitivity to midazolam.
- Acute narrow-angle glaucoma.

WARNINGS AND PRECAUTIONS

Cardiorespiratory Adverse Reactions: Serious cardio-respiratory adverse reactions have occurred, sometimes resulting in death or permanent neurologic injury.

Paradoxical Behavior: Agitation, involuntary movements (including tonic/clonic movements and muscle tremor), hyperactivity and combativeness have been reported in both adult and pediatric patients.

Dependence and Withdrawal with Long-Term Use: Use for several days to weeks may lead to physical dependence to midazolam. Do not abruptly discontinue midazolam. Gradually taper the dosage using a tapering schedule that is individualized to the patient.

Debilitation and Comorbid Considerations: Higher risk adult and pediatric surgical patients, elderly patients require lower dosages, whether or not concomitant sedating medications have been administered.

Risk of Intra-Arterial Injection: There have been limited reports of intraarterial injection of midazolam. Adverse events have included local reactions, as well as isolated reports of seizure activity in which no clear causal relationship was established.

Impaired Cognitive Function: Because of partial or complete impairment of recall, patients should not operate hazardous machinery or a motor vehicle until drug effects have subsided.

Hypotension and Seizure in Preterm Infants and Neonates: Avoid rapid injection in the neonatal population.

Neonatal Sedation and Withdrawal Syndrome: Receiving Midazolam in 0.9% Sodium Chloride Injection during pregnancy can result in neonatal sedation and/or neonatal withdrawal.

Pediatric Neurotoxicity: In developing animals, exposures greater than 3 hours cause neurotoxicity. Weigh benefits against potential risks when considering elective procedures in children under 3 years old.

ADVERSE REACTIONS

The most common adverse reactions (≥ 15%) were decreased tidal volume, decreased respiratory rate, and apnea.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176, option 5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

Opioid Analgesics and Other Sedative Hypnotics: Risk of respiratory depression is increased.

Cytochrome P450-3A4 Inhibitors: May result in prolonged sedation due to decreased plasma clearance of midazolam.

USE IN SPECIFIC POPULATIONS

Lactation: A lactating woman may pump and discard breast milk for 4 to 8 hours after treatment with midazolam.

INDICATIONS AND USE

Midazolam in 0.9% Sodium Chloride Injection is a benzodiazepine indicated for:

- Continuous intravenous infusion for sedation of intubated and mechanically ventilated adult, pediatric, and neonatal patients as a component of anesthesia or during treatment in a critical care setting.

This Important Safety Information does not include all the information needed to use Midazolam in Sodium Chloride Injection safely and effectively. Please see full prescribing information, including BOXED WARNING, for Midazolam in Sodium Chloride Injection. Full prescribing information is also available at www.fresenius-kabi.com/us.

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