MIDAZOLAM

Soother & Cool INZO Antifungal (OTC): 2% (56.7 g, 141.7 g).
Generic: 2% (15 g, 28.4 g, 30 g).
Cream, Vaginal: Midazolam 7 (OTC): 2% (45 g). Generic: 2% (45 g).
Kit, External: Fungoid Tincture (OTC): 2%.
Kit, Vaginal: GoodSense Miconazole 1 (OTC): Cream, topical: 2% (9 g) and Suppository, vaginal: 1200 mg.
Miconazole 3 Combo Pack (OTC): Cream, topical: 2% (9 g) and Suppository, vaginal: 200 mg (3).
Ointment, External: Aloe Vesta Antifungal (OTC): 2% (56 g, 141 g).
Aloe Vesta Clear Antifungal (OTC): 2% (56 g, 141 g).
Cr-Act-Clear AF (OTC): 2% (4, 57 g, 142 g).
DermaFungal (OTC): 2% (113 g).
Remedy Antifungal Clear (OTC): 2% (71 g).
Trifine Paste AF (OTC): 2% (28.7 g, 56.7 g).
Powder, External: Desenex (OTC): 2% (43 g, 85 g).
Lotrimin AF (OTC): 2% (90 g).
Micro Guard (OTC): 2% (85 g).
Remedy Antifungal (OTC): 2% (85 g).
Remedy Phytoplex Antifungal (OTC): 2% (71 g).
Zesaorf-af (OTC): 2% (71 g).
Solution, External: Azolin Tincture (OTC): 2% (29.57 mL).
Fungoid Tincture (OTC): 2% (29.57 mL).
Suppository, Vaginal: Miconazole 7 (OTC): 100 mg (7 ea).
Miconazole 3: 200 mg (3 ea).
Miconazole 7: 100 mg (7 ea).
Doseage Forms: International Exciption information presented when available (limited, particularly for generics);
consult specific product labeling. Note: Availability of specific dosage forms may vary by region/country.
Additional dosage forms not available in the US and/or Canada:
Capsule, Vaginal, as nitrate: 400 mg, 1,200 mg.
Miconazole Antifungal (OTC) see Miconazole (Topical) on page 1542.
Miconazole Nitrate see Miconazole (Topical) on page 1542.
MiCort-HC see Hydrocortisone (Topical) on page 1141.
Miconzole (Can) see Miconazole (Topical) on page 1542.
MiconRhOGAM Ultra-filtered Plus see Rh(D) Immune Globulin on page 2030.
Micro Guard (OTC) see Miconazole (Topical) on page 1542.
Micro-K see Potassium Chloride on page 1910.
Micro-K Extencaps (Can) see Potassium Chloride on page 1910.
MicroKlenz Wound Cleanser (OTC) see Sodium Chloride on page 2143.
Miconase see Glibenclamide [GlBuride] on page 1090.
Micronefin (OTC) [DCS] see Adrenaline [EPINEPHrine] (Oral Inhalation) on page 72.
Micronor (Can) see Norethisterone [Norethindrone] on page 1674.
Microzide see Hydrochlorothiazide on page 1134.
Mictoryl (Can) see Propipereine on page 1957.
Mictoryl Pediatric (Can) see Propipereine on page 1957.
Midamor see AMILoxide on page 130.

Midazolam

Brand Names: US Midazolam=Synspend SP FH4
Brand Names: Canada Midazolam Injection
Index Terms: Midazolam HCI; Midazolam Hydrochloride; Midazolam Maleate; Versed.
Pharmacologic Category Anticonvulsant, Benzodiazepine; Benzodiazepine
Sedation/Anxiety/Amnesia (Preoperative/properEcutional): IV: Preoperative sedation, anxiolysis, and amnesia. IM: Sedation, anxiolysis, and amnesia prior to or during diagnostic, therapeutic, or endoscopic procedures, or prior to surgery.
Oral (syrup): Sedation, anxiolysis, and amnesia in children prior to diagnostic, therapeutic or endoscopic procedures or before induction of anesthesia. Oral (tablets [International product]): Sedation prior to surgical or diagnostic procedures.
Sedation for mechanically-ventilated patients: IV: Sedation of intubated and mechanically-ventilated patients as a component of anesthesia or during treatment in a critical care setting by continuous IV infusion.

Pregnancy Considerations

Adverse events have not been observed in animal reproduction studies. Midazolam has been found to cross the human placenta and can be detected in the serum of the umbilical vein and artery, as well as the amniotic fluid. Teratogenic effects have been observed with some benzodiazepines; however, additional studies are needed. The incidence of premature birth and low birth weights may be increased following maternal use of benzodiazepines; hypoglycemia and respiratory problems in the neonate may occur following exposure late in pregnancy. Neonatal withdrawal symptoms may occur within days to weeks after birth and "floppy infant syndrome" (which also includes withdrawal symptoms) have been reported with some benzodiazepines (Bergman 1992, Iqbal 2002, Wikner 2007).

Based on animal data, repeated or prolonged use of general anesthetic and sedation medications that block N-methyl-D-aspartate (NMDA) receptors and/or potentiate gamma-aminobutyric acid (GABA) activity may affect brain development. Human data may be the most vulnerable during the third trimester. Until additional information is available, the benefits and risks of maternal treatment with midazolam during pregnancy should be evaluated, especially for procedures lasting more than 3 hours. ACOG recommends that pregnant women should not be medically indicated surgery or procedures, regardless of trimester. If the procedure is elective, it should be delayed until after delivery (ACOG 2011).

Breastfeeding Considerations

Midazolam and hydroxyzidine are present in breast milk.
The relative infant dose (RID) of midazolam is 0.35% when calculated using the highest breast milk concentration located and compared to a weight-adjusted maternal dose of 30 mg.
In general, breastfeeding is considered acceptable when an RID of a medication is <10% (Anderson 2016; Ito 2000).
The RID of midazolam was calculated using a milk concentration of 0.0001 mg/mL (30 nmol/L), providing an estimated daily infant dose via breast milk of 0.056 mg/kg/day. This milk concentration was obtained following accidental maternal administration of two oral doses of midazolam 15 mg (total dose: 30 mg) (Matheson 1990). In most reports, midazolam and hydroxyzidine concentrations in breast milk are below the limit of quantification 4 hours after a single dose (Kottabash 1997; Matheson 1990).

CNS depression was reported in infants following exposure to benzodiazepines via breast milk (study included exposures to midazolam) (Kelly 2012). The manufacturer recommends that caution be exercised when administering midazolam to breastfeeding women. Available guidelines suggest waiting for ≥24 hours after a maternal dose of midazolam to continue breastfeeding (Shergill 2012).

Contraindications

Hypersensitivity to midazolam or any component of the formulation; intrathecal or epidural injection of parenteral forms containing preservatives (ie, benzyl alcohol); acute narrow-angle glaucoma.
Concurrent use of oral midazolam with protease inhibitors (amprenavir, atazanavir, atazanavir-cobicistat, darunavir, indinavir, lopinavir-ritonavir, nelfinavir, ritonavir, saquinavir, tipranavir); concurrent use of oral or injectable midazolam with fosamprenavir.
Additional contraindications: reported for tablets [International product]: Severe respiratory insufficiency; severe hepatic insufficiency; sleep apnea syndrome; myocardial gravis; use in children and adolescents.
Dissociation: contraindication for benzodiazepines is limited. However, because of similarities in chemical structure and/or pharmacologic actions, the possibility of cross-sensitization cannot be ruled out with certainty.
Canadian labeling: Additional contraindications (not in US labeling): Hypersensitivity to benzodiazepines; acute pulmonary insufficiency; severe chronic obstructive pulmonary disease.
Midazolam

Warnings/Precautions [US Boxed Warning]: Has been associated with respiratory depression following airway pro-

Procedure, and personnel trained in their use and skilled in airway management should be assured. For deeply

Pediatric patients with cardiac or respiratory compromise caution in the elderly; decreased dosages recommended. Use with

Benzoiazepines have been associated with anterograde disadvantage of benzodiazepines and opioids may result in profound sedation,

Benzodiazepines have been associated with anterograde amnesia (Nelson 1999). May cause CNS depression, which may impair physical or mental abilities; patients midway through surgical or diagnostic procedures, and/or those with impaired alertness (eg, operating machinery or driving). A maximum of 1 day should elapse after midazolam admin-

Some dosage forms may contain benzyl alcohol; large amounts of benzyl alcohol (≥299 mg/kg/day) may be associated with a potentially fatal toxicity (“gasping syn-

Avoid concomitant use of Midazolam with any of the following:

Neonates are also vulnerable to profound and/or prolonged respiratory effects of midazolam. [US Boxed Warning]: Midazolam must never be used without individualization of dosage. The initial IV dose for sedation in adults may be as little as 1 mg, but should not exceed 2.5 mg in a healthy adult. Lower doses are necessary for older (over 60 years) or debilitated patients and in patients receiving concomitant opioids or other CNS depressants. The initial dose and subsequent doses should always be given 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 dilutions thereof should be limited to 1 mg/mL, and the use of this formulation is not 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 amounts of benzyl alcohol (≥299 mg/kg/day) may be associated with a potentially fatal toxicity (“gasping syn-

MIDAZOLAM

Drug Interactions

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Miscellaneous: Paradoxical reaction (children)

Local: injection site reaction (severity less than diaze-

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Duration of action after a single dose is determined by redistribution rather than metabolism. Tolerance develops to the sedative and anticonvulsant effects. Midazolam does not develop to the anxiolytic effects (Vinkers 2012). With

Use benzodiazepines with caution in patients with glaucoma, heart

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