# Midazolam Hydrochloride Syrup (midazolam hydrochloride) - Drug Summary

Paddock Laboratories, Inc.





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Midazolam Syrup
(midazolam hydrochloride)

## BOXED WARNING

Associated with respiratory depression and respiratory arrest, especially when used for sedation in noncritical care settings. Associated with reports of respiratory depression, airway obstruction, desaturation, hypoxia, and apnea, most often when used concomitantly with other CNS depressants (eg, opioids). Used only in hospital or ambulatory care settings that can provide continuous monitoring of respiratory and cardiac function. Assure immediate availability of resuscitative drugs and age- and size-appropriate equipment for ventilation and intubation, and personnel trained in their use and skilled in airway management. For deeply sedated patients, a dedicated individual, other than the practitioner performing the procedure, should monitor the patient throughout the procedure.

## COMMON BRAND NAMES

Versed Syrup (Discontinued), Midazolam Syrup

## THERAPEUTIC CLASS

Benzodiazepine

## DEA CLASS

CIV

## PEDIATRIC DOSAGE & INDICATIONS

### Sedation

**Sedation, Anxiolysis, and Amnesia Prior To Diagnostic, Therapeutic, or Endoscopic Procedures or Before Induction of Anesthesia:**

**≥6 Months of Age:**
Individualize dose based on age, level of anxiety, concomitant medications, and medical need
**Usual:** 0.25-0.5mg/kg single dose
**Max:** 20mg

**6 Months-<6 Years or Less-Cooperative Patients:**
May require higher than usual dose up to 1mg/kg

**6-<16 Years or Cooperative Patients:**
**Usual:** 0.25mg/kg

## DOSING CONSIDERATIONS

**Concomitant Medications**
**Narcotics or Other CNS Depressants:**
Consider 0.25mg/kg

**Other Important Considerations**
**W/ Cardiac or Respiratory Compromise/Higher-Risk Surgical Patients:**
Consider 0.25mg/kg
**Obese Patients:**
Calculate dose based on ideal body weight

## ADMINISTRATION

Oral route

Dispense medication from oral dispenser directly into mouth; do not mix w/ any liquid (eg, grapefruit juice) prior to dispensing

## HOW SUPPLIED

Syrup: 2mg/mL [118mL]

## CONTRAINDICATIONS

Acute narrow-angle glaucoma.

## WARNINGS/PRECAUTIONS

May be used with treated open-angle glaucoma. Not for chronic use. Continue monitoring vital signs during recovery period. Episodes of oxygen desaturation, respiratory depression, apnea, and airway obstruction markedly increased in patients with abnormal airway anatomy, cyanotic congenital heart disease, sepsis, or severe pulmonary disease. Agitation, involuntary movements (eg, tonic/clonic movements and muscle tremor), hyperactivity, and combativeness reported; consider possibility of paradoxical reaction and evaluate response to each dose of treatment and all other drugs before proceeding if these reactions occur. Patients with cardiac or respiratory compromise may be unusually sensitive to respiratory depressant effect. Patients undergoing procedures involving the upper airway (eg, upper endoscopy, dental care) are particularly vulnerable to episodes of desaturation and hypoventilation. Caution in patients with chronic hepatic disease, chronic renal failure, and congestive heart failure (CHF). May impair physical/mental abilities; caution to assure safe ambulation. May increase risk of congenital malformation during pregnancy.

## ADVERSE REACTIONS

Respiratory depression, airway obstruction, desaturation, hypoxia, apnea, emesis, nausea, laryngospasm.

## DRUG INTERACTIONS

See Boxed Warning. Caution with drugs known to inhibit CYP3A4. Drugs such as diltiazem, erythromycin, fluconazole, itraconazole, ketoconazole, saquinavir, and verapamil may increase levels, which may result in increased and prolonged sedation; may require lower doses of midazolam. Potent CYP3A4 inhibitors ritonavir and nelfinavir may cause intense/prolonged sedation and respiratory depression; use with caution and consider dose adjustments. CYP3A4 inducers (eg, rifampin, carbamazepine, phenytoin) may decrease levels; use with caution and consider dose adjustments. Inadequate sedation reported during coadministration of chloral hydrate and later with methylphenidate. CNS depressants, particularly narcotics (eg, morphine, meperidine, fentanyl), propofol, ketamine, nitrous oxide, secobarbital, and droperidol may accentuate sedative effect; adjust dose of midazolam accordingly. Barbiturates, alcohol, or other CNS depressants may contribute to profound and/or prolonged drug effect. Narcotic premedication may depress ventilatory response to carbon dioxide stimulation. Mild to deep sedation levels with potential loss of protective reflexes may occur with anesthetic agents or other CNS depressants.

## PREGNANCY AND LACTATION

Category D, caution in nursing.

## MECHANISM OF ACTION

Benzodiazepine; appear to result from reversible interactions with the gamma-aminobutyric acid benzodiazepine receptor in the CNS, the major inhibitory neurotransmitter in the CNS.

## PHARMACOKINETICS

**Absorption:** Rapid. Absolute bioavailability (36%). Variable doses and age of patient resulted in different pharmacokinetic parameters. **Distribution:** $V_d$=1.24-2.02L/kg (IV; plasma protein binding (97%; 89% α-hydroxymidazolam); found in breast milk; crosses the placenta. **Metabolism:** Liver and gut by CYP3A4 to α-hydroxymidazolam (active metabolite). **Elimination:** Urine (63-80% as α-hydroxymidazolam glucuronide); $T_{1/2}$=2.2-6.8 hrs. Refer to PI for additional pharmacokinetic information.

## ASSESSMENT

Assess for known hypersensitivity to drug, acute narrow-angle glaucoma, untreated open-angle glaucoma, cardiac/respiratory compromise, CHF, patients undergoing procedures involving the upper airway, renal/hepatic impairment, pregnancy/nursing status, and for possible drug interactions.

## MONITORING

Monitor for hypersensitivity reactions, cardiorespiratory depression, paradoxical reactions, and other adverse reactions. Monitor for early signs of hypoventilation, airway obstruction and apnea. Perform continuous monitoring of cardiac and respiratory function. Monitor vital signs during recovery period.

## PATIENT COUNSELING

Advise to inform physician about alcohol consumption and any concomitant medications currently taking. Instruct to notify physician if pregnant, planning to become pregnant, or if breastfeeding. Inform of the pharmacological effects (eg, sedation and amnesia) of medication. Advise not to take grapefruit juice.

## STORAGE

20-25°C (68-77°F).

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