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Intervenous VERSED has been associated with respiratory depression and respiratory arrest, especially when used for conscious sedation. In some cases, this was not recognized promptly and treated effectively, death or hypoxic encephalopathy may be reported. Intervenous VERSED should not be used only in hospital or ambulatory care settings, including physicians offices, that provide for continuous monitoring of respiratory and cardiac function. Immediate availability of resuscitative drugs and personnel trained in their use should be assured. (See WARNINGS.)

The initial intervenous dose for conscious sedation may be as little as 1 mg, but should not exceed 5 mg. Oral health care professionals and patients receiving concomitant narcotics or other CNS depressants. The initial dose and all subsequent doses should never be given as a bolus, administer over at least 2 minutes and allow an additional 2 or more minutes to fully evaluate the sedative. 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. Consult complete product information under DOSAGE AND ADMINISTRATION for complete dosing information.

CONTRAINdications: Patients with known hypersensitivity to the drug. Benzodiazepines are contraindicated in patients with acute narrow angle glaucoma; may be used in open angle glaucoma only if patients are receiving appropriate therapy. WARNINGS: Never use in individualization of dosage. Prior to IV use in any dose, assure immediate availability of oxygen, resuscitative equipment and skilled personnel for maintenance of a patent airway and support of ventilation. Concomitantly monitor patients for signs of undiluted VERSED or plasma, which can lead to hypoxia/ cardiac arrest unless effective countermeasures are taken immediately. Vitals signs should continue to be monitored during the recovery period. Be alert for the onset of respiratory depression, and be prepared to treat it. Patients can die by this depression, it should be administered as an induction agent only by a person trained in general anesthesia and should be used for conscious sedation only in the absence of personnel trained in early detection and management of a patent airway and supporting ventilation. For conscious sedation, do not administer IV by rapid or single bolus. Serious cardiorespiratory adverse events have occurred These have included respiratory depression, apnea, respiratory arrest and cardiac arrest, sometimes resulting in death. There have been rare reports of hypertensive episodes requiring treatment during or after diagnostic or surgical manipulations in patients who have received VERSED. Hypertension occurred more frequently in the conscious sedation studies in patients premedicated with narcotic. Reactions such as agitation, involuntary movements, hyperactivity and combativeness have also been reported. This is due to reaction to the patient, not the drug administration; however, the possibility of cerebral hypoxa or true paradoxical reactions should be considered. Should these reactions occur, response to each dose of VERSED and all other drugs should be evaluated before proceeding.

Concomitant use of barbiturates, alcohol or other CNS depressants may increase the risk of undersedation or apnea and may contribute to profound and/or prolonged drug effect. Narcotic premedication also depresses the ventilatory response to carbon dioxide stimulation. Higher risk surgical elderly or debilitated patients require lower dosages for induction of anesthesia, premmedication or not. Patients with chronic obstructive pulmonary disease are unusually sensitive to the respiratory depressant effect of VERSED. Patients with chronic renal failure and patients with congestive heart failure eliminate midazolam much more slowly. Because patients frequently have inefficient function of one or more organ systems, and because dosage requirements have been shown to decrease with age, reduce initial dosage and consider possibility of a profound and/or prolonged effect.

Do not administer in shock, coma, acute alcohol intoxication with depression of vital signs. Particular care should be exercised in the use of IV VERSED in patients with undiagnosed acute abdomen, in patients with undiagnosed anaphylaxis, or in patients with other conditions which may result in hypotension. Guard against unintended intra-articular injection: hazards in humans unknown. Avoid extravasation.

Gross tests of recovery from the effects of VERSED cannot alone predict reaction time under stress. This drug is not used alone during anesthesia, and the contribution of other perioperative drugs and events can vary. The decision to as when patients may engage in activities requiring mental alertness must be individualized; it is recommended that no patient should operate hazardous machinery or a motor vehicle until the effects of the drug, such as drowsiness, have subsided or until the day after anesthesia, whichever is longer.

Usage in Pregnancy: An increased risk of congenital malformations associated with exposure of benzodiazepines (diazepam and chlordiazepoxide) has been suggested in several studies. If VERSED is used during pregnancy, apprise the patient of the potential hazard to the fetus.

PREGNANCY: Although intervenous doses in elderly and debilitated patients. These patients will also probably take longer to recover completely after VERSED by induction of anesthesia.

VERSED does not protect against increased intracranial pressure or against the heart rate rise and/or blood pressure rise associated with endocardial inulation under light general anesthesia.

Information for patients: Communicate the following information and instructions to the patient when appropriate:
1. Inform your physician about any alcohol consumption and medical you are now taking, including nonprescription drugs. Alcohol has an increasing effect on patients when combined with benzodiazepines; therefore, caution should be exercised regarding simultaneous ingestion of alcohol and benzodiazepines. Inform your physician if you are pregnant or planning to become pregnant. Inform your physician if you are nursing.

Drug interactions: The sedative effect of IV VERSED is augmented by premedication, particularly narcotics (e.g., morphine, meperidine, fentanyl) and also secobarbital and Innovar. The sedative effects of midazolam and diazepam. Consequently, adjust the dosage according to the type and amount of premedication.

VERSED* (brand of midazolam HCI/Roche) INJECTION

A moderate reduction in induction dosage requirements of thiopental (about 15%) has been noted following use of IV VERSED for premedication. IV administration of VERSED decreases the minimum alveolar concentration (MAC) of halothane required for general anesthesia. This decrease correlates with the dose of VERSED administered.

Although the possibility of minor interactional effects has not been fully studied, VERSED and paralyzing agents may have been used together in patients without noting clinically significant changes in dosage, onset or duration. VERSED does not protect against the characteristic circulatory changes noted after administration of succinylcholine or pancuronium, or against the increased intracranial pressure noted following administration of succinylcholine. VERSED does not cause a clinically significant change in dosage, onset or duration of a single intubating dose of succinylcholine. No significant adverse interactions with commonly used premedications or drugs used during anesthesia and surgery (including atropine, scopolamine, glycopyrrolate, dexamethasone, halothane, diazepam, hydroxyzine, ilupine, succinylcholine and nondepolarizing muscle relaxants) or topical local anesthetics (including lidocaine, dyclonine HCI and Celamine) have been observed.

Drugabuse/ laboratory test interactions: Midazolam has not been shown to interfere with clinical laboratory test results.

Carcinogenesis, mutagenesis, impairment of fertility: Midazolam maleate was administered to mice and rats for two years. At the highest dose (60 mg/kg/day) female mice had a marked increase in incidence of hepatic tumors and male rats had a small but significant increase in benign thyroid follicular cell tumors. These tumors were found after chronic use, whereas human use will ordinarily be of single or several doses. Midazolam did not have mutagenic effects in tests conducted.

A reproduction study in rats did not show any impairment of fertility at up to ten times the human IV dose.

Pregnancy: Teratogenic effects: Pregnancy Category D. See WARNINGS section. Midazolam maleate injectable at 5 and 10 times the human dose, did not show evidence of teratogenicity in rabbits and rats. Labor and delivery: There was no evidence of increased complications. As with other benzodiazepines given in the last weeks of pregnancy have resulted in neonatal CNS depression. VERSED is not recommended for use in obstetric use.

Nursing mothers: It is not known whether midazolam is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when breastfed.

Pediatric use: Safety and effectiveness in children below the age of 18 years has not been established.

ADVERSE REACTIONS: See WARNINGS concerning serious cardiorespiratory events and possible paradoxical reactions. Fluctuations in vital signs following general anesthesia were the most frequently seen findings; and included decreases in arterial blood pressure, heart rate and respiratory rate decrease (23 3% of patients following IV and 10 8% of patients following IM administration) and apnea (15 4% of patients following IV administration), as well as variations in blood pressure and pulse rate. Following IV injection headache (1 3%), local effects at IM site (pain (3 9%), redness (0 5%), muscle stiffness (0 3%). Following IV administration hiccoughs (3 9%), nausea (2 8%), vomiting (2 6%), coughing (1 2%), oversedation (1 6%), headache (1 5%), drowsiness (1 2%), local effects at IV site (tenderness (5 8%), pain during injection (5 0%), redness (2 6%), oversedation (1 7%), phlebitis (0 4%). Other effects (5%) mainly following IV administration: Respiratory: Laryngospasm, bronchospasm, dyspnea. Hyperventilation: wheezing, shallow respirations, airway obstruction, tachypnea. Cardiovascular: Bigeminy, premature ventricular contractions, vasovagal episode, tachycardia, nystagmus, diaphoresis, muscle aches, faint feeling, hematoma. Miscellaneous: Pruritus, nausea, vomiting, coughing, dyspnea, hypertension, hypotension, flushing, dizziness, drowsiness, nausea, vomiting, diaphoresis, pruritus, rash, induration, phlebitis (0 4%). Other local effects include pain, injection site, rash, pruritus. Miscellaneous: Fainting, lightheadedness, chills, weakness, toothache, taint, feeling, hematoma.

Drug Abuse and Dependence: Available data concerning the drug abuse and dependence potential of midazolam suggest that its abuse potential is at least equivalent to that of diazepam.

OVERDOSAGE: Manifestations would resemble those observed with other benzodiazepines (e.g., sedation, somnolence, confusion, impaired coordination, diminished reflexes, coma, untoward effects on visual signs) No specific organ toxicity was expected.

DOSE AND ADMINISTRATION: VERSED is a potent sedative agent which requires slow administration and individualization of dosage. Clinical experience has shown VERSED to be 3 to 4 times as potent per mg as diazepam. BECAUSE SERIOUS AND LIFE-THREATENING OR RESPIRATORY ADVERSE EVENTS HAVE BEEN REPORTED, PROPER FOR MONITORING, DETECTION AND CORRECTION OF THESE REACTIONS MUST BE MADE FOR EVERY PATIENT TO Whom VERSED INJECTION IS ADMINISTERED, REGARDLESS OF AGE OR HEALTH STATUS, EXCESSIVE SEDATION OR SLENDER INJECTIONS MAY RESULT IN RESPIRATORY DEPRESSION AND/OR ARREST. (See WARNINGS.) Prior to use refer to the DOSAGE AND ADMINISTRATION section in the complete Product Information.
THE STRENGTHS YOU NEED
Color-coded for convenience

1 mg/mL

For I.V. Conscious Sedation
Color-coded orange in 2-mL, 5-mL and 10-mL vials

For Premedication, Induction and Maintenance of Anesthesia
1 mg/mL color-coded orange in 2-mL, 5-mL and 10-mL vials
5 mg/mL color-coded green in 1-mL, 2-mL, 5-mL and 10-mL vials
and 2-mL Tel-E-Ject® Disposable Syringes

INJECTABLE
VERSED®
midazolam HCl/Roche®
INSTEAD

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Please see summary of product information on adjacent page.