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Intravenous VERSED has been associated with respiratory depression and respira-
tory arrest, especially when used for conscious sedation. In some cases, where
this effect was not recognized, fatal hypercarbia, hypercapnia, or hypoxemia
with/without respiratory arrest or death has resulted. Intravenous VERSED should be used only in hos-
pital or ambulatory care settings, including physicians’ offices, that provide for
continuous monitoring of respiratory and cardiac function. Immediate availability
of resuscitative drugs and equipment and personnel trained in their use should be
assured (See WARNINGS).

The initial intravenous dose for conscious sedation may be as little as 1 mg, but
should not exceed 3 mg. Because the rates of blood flow and volume of distribution
for older (over 60 years) or debilitated patients and in patients receiving concomi-
tant 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 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. Consult complete product information
under DOSAGE AND ADMINISTRATION for complete dosing information.

CONTRAINDICATIONS: Patients with known hypersensitivity to the drug. Benzo-
diazepines are contraindicated in patients with acute narrow angle glaucoma, may
be contraindicated in patients with open angle glaucoma only if patients are receiving appropriate therapy.

WARNINGS: Never use without individualization of dosage. Prior to IV use in
any dose, ensure immediate availability of oxygen, resuscitative equipment and
trained personnel for maintenance of a patent airway and support of venti-
lation. Continuously monitor for early signs of underventilation or apnea, which
may lead to hypoxia/carbon arrest unless effective countermeasures are taken
immediately. Vital signs should continue to be monitored during the recovery period.
IV VERSED depresses respiration, and opioid agonists and other sedatives can add to 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 context of ongoing cardiovascular monitoring (e.g., electrocardiogram moni-
tion), maintaining a patent airway and supporting ventilation. For conscious seda-
tion, do not administer IV by rapid or single bolus. Serious cardiorespiratory adverse events have occurred. These have included respiratory depression, apnea, respiratory arrest or death, severe hypotension, or death. There have been rare reports of hypotensive episodes requiring treatment during or after diag-
nostic or surgical manipulations in patients who have received VERSED. Hypotension occurred more frequently in the conscious sedation studies in patients premedicated with narcotic.

Reactions such as agitation, involuntary movements, hyperactivity and combativeness
have been reported. These may be due to inadequate or excessive dosing or improper
administration; however, the possibility of cerebral hypoxia 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 underventilation or apnea and may contribute to profound and/or prolonged
drug effect. Narcotic premedication also depresses the ventilatory response to carbon
dioxide stimulation.

Hypotension, surgical, elderly or debilitated patients require lower doses for induction
of anesthesia, premedication 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 more slowly. Because elderly 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
drug 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
uncontrolled hypertension such as severe hypertension, retroperitoneal effusion,
Guard against unintended intra-arterial injection, hazards in humans, unknown.
Avoid extravasation.

Gross tests of recovery from the effects of VERSED cannot alone predict reaction time
under normal circumstances. This drug should not be used alone during anesthesia, and the contraindication
of other perioperative drugs and events can vary. The decision as to when patients may
engage in activities requiring mental alertness must be individualized, it is recom-
mended 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 aner-
thesis; whichever is longer.

USES IN PREGNANCY: The increased risk of congenital malformations associated
with the use 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.

PRECAUTIONS: Use with caution in patients where intravenous doses in elderly and debilitated
patients. These patients will also probably take longer to recover completely after
VERSED for induction of anesthesia

VERSED should not be used against increased intracranial pressure or against the heart
rate rise and/or blood pressure rise associated with endotracheal intubation under
light general anesthesia

Information for patients: Communicate the following information and instructions to
the patient before any administration of any alcohol, sedative, hypnotic or
medication you are now taking, including nonprescription drugs. Alcohol has an
increased effect when consumed with benzodiazepines. Therefore, caution should be
exercised regarding simultaneous ingestion of alcohol and benzodiazepines.

REFERENCES: 1. Data on file (Doc. #069-001), Roche Laboratories. 2. VERSED®
(brand of midazolam HCI/Roche) (C, Scientific Summary, Roche Laboratories, a

VERSED® (brand of midazolam HCI/Roche) (C)

INJECTION

Before prescribing, please consult complete product information, a summary of
which follows:

Do not administer

VERSED® (brand of midazolam HCI/Roche) (C)

INJECTION

Before prescribing, please consult complete product information, a summary of
which follows:

Do not administer

VERSED® (brand of midazolam HCI/Roche) (C)

INJECTION

Before prescribing, please consult complete product information, a summary of
which follows:

Do not administer

VERSED® (brand of midazolam HCI/Roche) (C)

INJECTION

Before prescribing, please consult complete product information, a summary of
which follows:

Do not administer
VERSED®
midazolam HCl/Roche IV
INSTEAD
...of hydroxyzine

• Sedates faster¹

Desirable Level of Sedation at 15 minutes:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Desired Level</th>
<th>hydroxyzine</th>
</tr>
</thead>
<tbody>
<tr>
<td>VERSED</td>
<td>43% (64/149)</td>
<td>19% (19/101)</td>
</tr>
<tr>
<td>hydroxyzine</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

• Virtually painless at I.M. injection site²

Incidence of Pain:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Incidence of Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>VERSED</td>
<td>4.5% (12/269)</td>
</tr>
<tr>
<td>hydroxyzine</td>
<td>47.1% (64/136)</td>
</tr>
</tbody>
</table>

• Pronounced amnestic effect²

VERSED is 3 to 4 times as potent per mg as diazepam. Individualize dose. Reduced doses may be sufficient in the elderly and debilitated. Caution patients about driving or operating hazardous machinery after receiving VERSED.

VERSED INJECTABLE
brand of midazolam HCl Roche IV

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Please see references and summary of product information on adjacent page.