

## Valium advertisement.

[s.l.]: [s.n.], 1972

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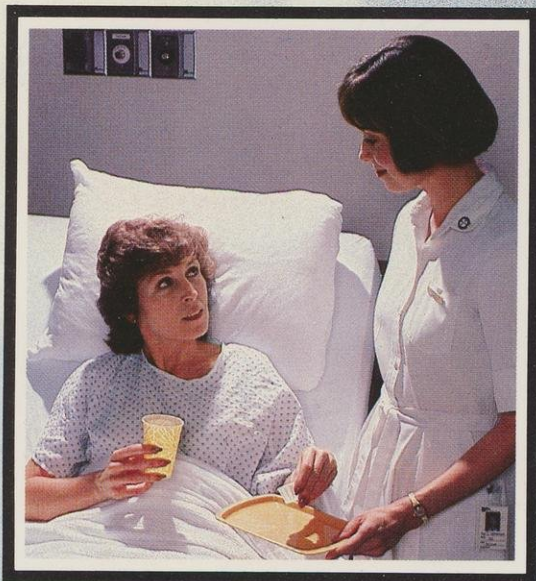
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# INVASIVE PROCEDURES...

On the eve of surgery, anxiety can reach excessive levels. At such times, oral Valium (diazepam/Roche) is often especially useful. Its dependable calming action rapidly relieves anxiety—helps assure a more tranquil preoperative night. And Valium is well tolerated by most patients: side effects more serious than fatigue, drowsiness or ataxia are rare.

the night before



Oral  
**VALIUM**<sup>®</sup>  
diazepam/Roche

scored tablets



2 mg



5 mg

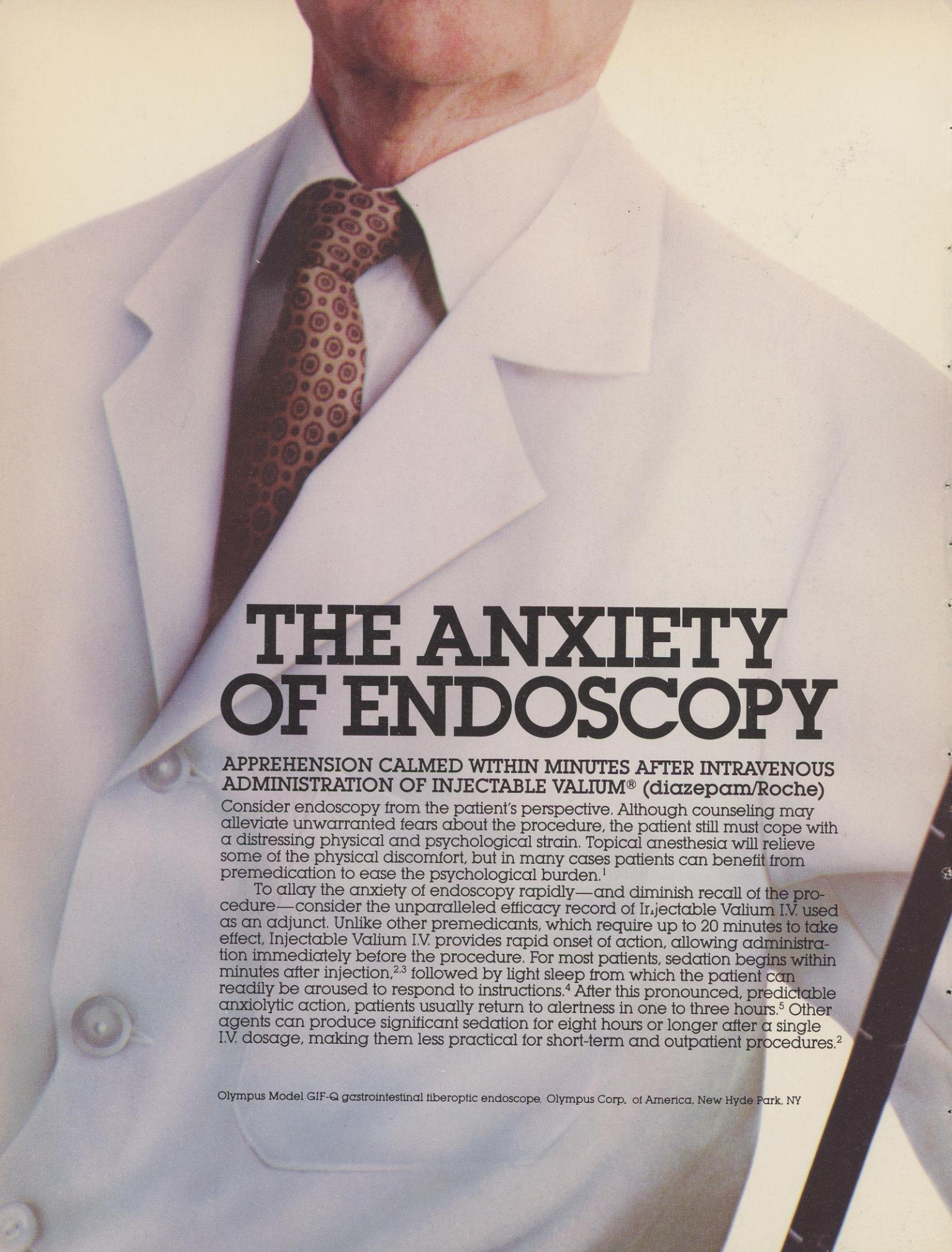


10 mg

Note our  
distinctive look

to control  
mounting anxiety





# THE ANXIETY OF ENDOSCOPY

## APPREHENSION CALMED WITHIN MINUTES AFTER INTRAVENOUS ADMINISTRATION OF INJECTABLE VALIUM® (diazepam/Roche)

Consider endoscopy from the patient's perspective. Although counseling may alleviate unwarranted fears about the procedure, the patient still must cope with a distressing physical and psychological strain. Topical anesthesia will relieve some of the physical discomfort, but in many cases patients can benefit from premedication to ease the psychological burden.<sup>1</sup>

To allay the anxiety of endoscopy rapidly—and diminish recall of the procedure—consider the unparalleled efficacy record of injectable Valium I.V. used as an adjunct. Unlike other premedicants, which require up to 20 minutes to take effect, injectable Valium I.V. provides rapid onset of action, allowing administration immediately before the procedure. For most patients, sedation begins within minutes after injection,<sup>2,3</sup> followed by light sleep from which the patient can readily be aroused to respond to instructions.<sup>4</sup> After this pronounced, predictable anxiolytic action, patients usually return to alertness in one to three hours.<sup>5</sup> Other agents can produce significant sedation for eight hours or longer after a single I.V. dosage, making them less practical for short-term and outpatient procedures.<sup>2</sup>

Olympus Model GIF-Q gastrointestinal fiberoptic endoscope, Olympus Corp. of America, New Hyde Park, NY



AUG 9 1985

# OPERATIVE PERIOD

## to diminish recall

**Diminishes recall of unpleasant or painful procedures** When patients have vivid memories of invasive procedures, they may be less than willing to undergo such procedures again, even if they are medically necessary.<sup>8,9</sup> Recall of procedures such as endotracheal intubation can be diminished by the rapid-acting amnesic effect of Injectable Valium (diazepam/Roche) I.V. Anterograde amnesia usually begins within three minutes after a single I.V. injection, peaks within ten minutes and lasts for 20 to 60 minutes.<sup>3,10,11</sup>

This predictable pattern of action distinguishes Injectable Valium from other agents that can produce amnesia and sedation. Other agents can take 15 to 30 minutes to achieve the desired effect, and the effects may last for 24 hours or more.<sup>2</sup> However, patients should be warned about driving or performing other potentially dangerous activities after receiving Injectable Valium.

**Easily titrated for desired effect** The compact 10-mg prefilled syringe makes individualized titration of Injectable Valium (diazepam/Roche) simple because there is convenient, easily readable milligram calibration on both sides of the barrel. And unlike other injectable agents, Injectable Valium needs no reconstitution before administration and no refrigeration during storage. Do not mix or dilute Valium with other drugs or solutions. Administer slowly in a large vein or through the infusion line as close to the vein insertion site as possible.

Injectable Valium. In a class by itself for rapidly relieving anxiety and diminishing recall.

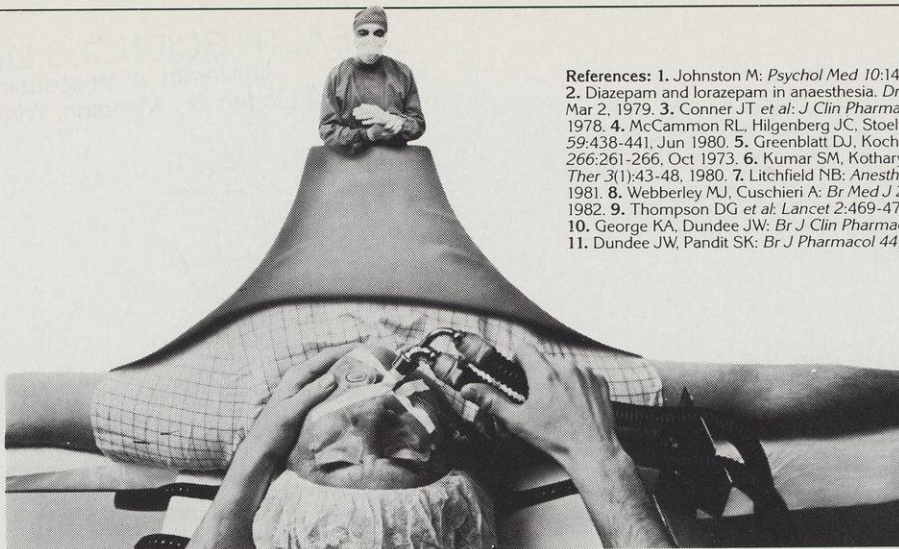
## Prompt Predictable INJECTABLE VALIUM<sup>®</sup> I.V. diazepam/Roche<sup>®</sup> (IV)

Ready-to-use Tel-E-Ject<sup>®</sup> disposable syringes } 5 mg/ml  
2-ml ampuls, 10-ml vials }



See next page for  
references and summary  
of product information.





- References:** 1. Johnston M: *Psychol Med* 10:145-152, Feb 1980.  
2. Diazepam and lorazepam in anaesthesia. *Drug Ther Bull* 17:19-20, Mar 2, 1979. 3. Conner JT et al: *J Clin Pharmacol* 18:285-292, May-Jun 1978. 4. McCammon RL, Hilgenberg JC, Stoelting RK: *Anesth Analg* 59:438-441, Jun 1980. 5. Greenblatt DJ, Koch-Weser J: *Am J Med Sci* 266:261-266, Oct 1973. 6. Kumar SM, Kothary SP, Zsigmond EK: *Clin Ther* 3(1):43-48, 1980. 7. Litchfield NB: *Anesth Prog* 29:11-17, Jan-Feb, 1981. 8. Webberley MJ, Cuschieri A: *Br Med J* 285:251-252, Jul 24, 1982. 9. Thompson DG et al: *Lancet* 2:469-470, Aug 30, 1980.  
10. George KA, Dundee JW: *Br J Clin Pharmacol* 4:45-50, Feb 1977.  
11. Dundee JW, Pandit SK: *Br J Pharmacol* 44:140-144, Jan 1972.

# INJECTABLE VALIUM<sup>®</sup> (diazepam/Roche) ©

Please consult complete product information, a summary of which follows:

**Indications:** Management of anxiety disorders, or short-term relief of symptoms of anxiety. Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic. Symptomatic relief of acute agitation, tremor, impending or acute delirium tremens and hallucinosis due to acute alcohol withdrawal; adjunctively in: relief of skeletal muscle spasm due to reflex spasm to local pathology; spasticity caused by upper motor neuron disorders; athetosis; stiff-man syndrome; tetanus; status epilepticus, severe recurrent seizures; adjunctively in anxiety, tension or acute stress reactions prior to endoscopic/surgical procedures; cardioversion.

**Contraindications:** Hypersensitivity; acute narrow angle glaucoma; may be used in patients with open angle glaucoma receiving appropriate therapy.

**Warnings:** To reduce the possibility of venous thrombosis, phlebitis, local irritation, swelling and, rarely, vascular impairment when used IV: inject slowly, taking at least one minute for each 5 mg (1 ml) given; do not use small veins, i.e., dorsum of hand or wrist; use extreme care to avoid intra-arterial administration or extravasation. Do not mix or dilute Valium with other solutions or drugs in syringe or infusion flask. If it is not feasible to administer Valium directly I.V., it may be injected slowly through the infusion tubing as close as possible to the vein insertion.

Administer with extreme care to elderly, very ill, those with limited pulmonary reserve because of possibility of apnea and/or cardiac arrest; concomitant use of barbiturates, alcohol or other CNS depressants increases depression with increased risk of apnea; have resuscitative facilities available. When used with narcotic analgesic, eliminate or reduce narcotic dosage at least 1/3, administer in small increments. Should not be administered to patients in shock, coma, acute alcoholic intoxication with depression of vital signs. As with most CNS-acting drugs, caution against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Has precipitated tonic status epilepticus in patients treated for petit mal status or petit mal variant status.

Withdrawal symptoms similar to those with barbiturates and alcohol have been observed with abrupt discontinuation after long use of excessive doses. Infrequently, milder withdrawal symptoms have been reported following abrupt discontinuation of benzodiazepines after long, continuous use at high therapeutic levels. After extended therapy, gradually taper dosage.

**Use in Pregnancy:** Use of minor tranquilizers during first trimester should almost always be avoided because of increased risk of congenital malformations, as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

Not recommended for OB use.

Efficacy/safety not established in neonates (age 30 days or less); prolonged CNS depression observed. In children, give slowly (up to 0.25 mg/kg over 3 minutes) to avoid apnea or prolonged somnolence; can be repeated after 15 to 30 minutes. If no relief after third administration, appropriate adjunctive therapy is recommended.

**Precautions:** Although promptly controlled, seizures may return; readminister if necessary; not recommended for long-term maintenance therapy. If combined with other psychotropics or anticonvulsants, carefully consider individual pharmacologic effects—particularly with known compounds which may potentiate action of Valium (diazepam/Roche), i.e., phenothiazines, narcotics, barbiturates, MAO inhibitors, antidepressants. Protective measures indicated in highly anxious patients with accompanying depression who may have suicidal tendencies. Observe usual precautions in impaired hepatic function; avoid accumulation in patients with compromised kidney function. Laryngospasm/increased cough reflex are possible during peroral endoscopic procedures; use topical anesthetic, have necessary countermeasures available. Hypotension or muscular weakness possible, particularly when used with narcotics, barbiturates or alcohol. Use lower doses (2 to 5 mg) for elderly/debilitated.

The clearance of Valium and certain other benzodiazepines can be delayed in association with Tagamet (cimetidine) administration. The clinical significance of this is unclear.

**Adverse Reactions:** Drowsiness, fatigue, ataxia, venous thrombosis/phlebitis at injection site, confusion, depression, dysarthria, headache, hypoaesthesia, slurred speech, syncope, tremor, vertigo, constipation, nausea,

incontinence, changes in libido, urinary retention, bradycardia, cardiovascular collapse, hypotension, blurred vision, diplopia, nystagmus, urticaria, skin rash, hiccups, changes in salivation, neutropenia, jaundice. Paradoxical reactions such as acute hyperexcited states, anxiety, hallucinations, increased muscle spasticity, insomnia, rage, sleep disturbances, stimulation have been reported; should these occur, discontinue drug. Cough, depressed respiration, dyspnea, hyperventilation, laryngospasm/pain in throat and chest have been reported in peroral endoscopic procedures. Isolated reports of neutropenia, jaundice; periodic blood counts, liver function tests advisable during long-term therapy. Minor EEG changes, usually low-voltage fast activity, of no known significance.

**Dosage:** Usual initial dose in older children and adults is 2 to 20 mg I.M. or I.V., depending on indication and severity. Larger doses may be required in some conditions (tetanus). In acute conditions injection may be repeated within 1 hour, although interval of 3 to 4 hours is usually satisfactory. Lower doses (usually 2 to 5 mg) with slow dosage increase for elderly or debilitated patients and when sedative drugs are added. (See Warnings and Adverse Reactions.)

For dosages in infants and children see below; have resuscitative facilities available.

**I.M. use:** by deep injection into the muscle.

**I.V. use:** inject slowly, take at least one minute for each 5 mg (1 ml) given. Do not use small veins, i.e., dorsum of hand or wrist. Use extreme care to avoid intra-arterial administration or extravasation. Do not mix or dilute Valium with other solutions or drugs in syringe or infusion flask. If it is not feasible to administer Valium directly I.V., it may be injected slowly through the infusion tubing as close as possible to the vein insertion.

Moderate anxiety disorders and symptoms of anxiety, 2 to 5 mg I.M. or I.V. and severe anxiety disorders and symptoms of anxiety, 5 to 10 mg I.M. or I.V., repeat in 3 to 4 hours if necessary; acute alcohol withdrawal, 10 mg I.M. or I.V. initially, then 5 to 10 mg in 3 to 4 hours if necessary. Muscle spasm, in adults, 5 to 10 mg I.M. or I.V. initially, then 5 to 10 mg in 3 to 4 hours if necessary (tetanus may require larger doses); in children, administer I.V. slowly; for tetanus in infants over 30 days of age, 1 to 2 mg I.M. or I.V., repeat every 3 to 4 hours if necessary; in children 5 years or older, 5 to 10 mg repeated every 3 to 4 hours as needed. Respiratory assistance should be available.

Status epilepticus, severe recurrent convulsive seizures (I.V. route preferred), 5 to 10 mg adult dose administered slowly, repeat at 10- to 15-minute intervals up to 30 mg maximum. Repeat in 2 to 4 hours if necessary, keeping in mind possibility of residual active metabolites. (Use caution in presence of chronic lung disease or unstable cardiovascular status. Infants (over 30 days) and children (under 5 years), 0.2 to 0.5 mg slowly every 2 to 5 min., up to 5 mg (I.V. preferred). Children 5 years plus, 1 mg every 2 to 5 min., up to 10 mg (slow I.V. preferred); repeat in 2 to 4 hours if needed. EEG monitoring may be helpful.

In endoscopic procedures, titrate I.V. dosage to desired sedative response, generally 10 mg or less but up to 20 mg (if narcotics are omitted) immediately prior to procedure; if I.V. cannot be used, 5 to 10 mg I.M. approximately 30 minutes prior to procedure. As preoperative medication, 10 mg I.M.; in cardioversion, 5 to 15 mg I.V. within 5 to 10 minutes prior to procedure. Once acute symptomatology has been properly controlled with injectable form, patient may be placed on oral form if further treatment is required.

**Management of Overdosage:** Manifestations include somnolence, confusion, coma, diminished reflexes. Monitor respiration, pulse, blood pressure; employ general supportive measures, I.V. fluids, adequate airway. Hypotension may be combated by the use of levaterenol or metaraminol. Dialysis is of limited value.

**Supplied:** Ampuls, 2 ml, boxes of 10; Vials, 10 ml, boxes of 1 and 10; Tel-E-Ject<sup>®</sup> (disposable syringes), 2 ml, boxes of 10. Each ml contains 5 mg diazepam compounded with 40% propylene glycol, 10% ethyl alcohol, 5% sodium benzoate and benzoic acid as buffers, and 1.5% benzyl alcohol as preservative.



Manufactured by Hoffmann-La Roche Inc.  
Nutley, New Jersey 07110  
Distributed by Roche Products Inc.  
Manati, Puerto Rico 00701



# THROUGHOUT THE PERI- to relieve excessive anxiety

## Rapid relief of anxiety and apprehension

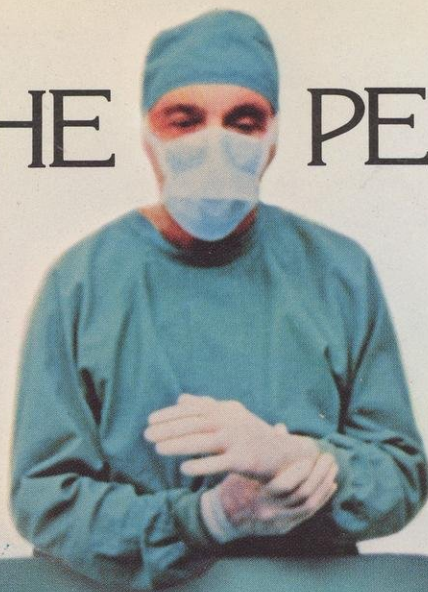
Anxiety is an extremely common reaction to the stress of anesthesia and surgery. Often at its most acute stage in the minutes just before induction, anxiety may even affect the outcome of the surgical procedure.<sup>1</sup>

To relieve anxiety promptly and predictably, no agent is more effective than Injectable Valium® (diazepam/Roche) I.V.

Within minutes after an I.V. injection,<sup>2,3</sup> most patients become noticeably calmer, sedated yet easily aroused if necessary. This response is prompt and predictable—just the kind you want in the anxious moments before surgery.

## Rarely compromises cardiac or respiratory function

Injectable Valium rarely produces clinically significant alterations in basal circulatory parameters.<sup>4-6</sup> In a series of 16,000 patients, apnea occurred in only three patients given Injectable Valium intravenously.<sup>7</sup> However, caution should be taken when administering the agent to elderly or debilitated patients with limited pulmonary reserve. Resuscitative equipment should be available for all patients, and narcotics should be reduced by one-third or more; in some cases they may be eliminated.







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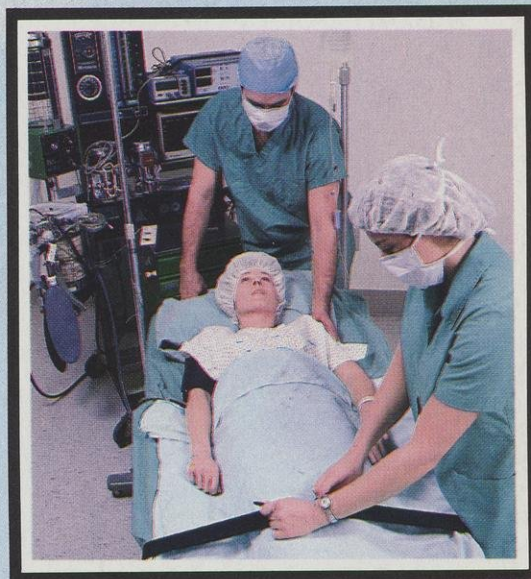
FEB 12 1985

# PERVASIVE ANXIETY

With Injectable Valium (diazepam/Roche) I.V., the course of action is predictable: its calming effect usually occurs within minutes,<sup>1,2</sup> bringing acute anxiety and apprehension under rapid control. Most patients are relaxed but still able to follow simple instructions. Anterograde amnesia also begins in minutes, rarely persists beyond an hour.<sup>2-6</sup> Although Injectable Valium has an excellent safety record, resuscitative facilities should be readily available. Narcotic dosage should be reduced by at least one-third. For warnings and precautions, see complete product information.

minutes before  
*Injectable*  
**VALIUM<sup>®</sup> I.V.**  
*diazepam/Roche<sup>®</sup>*

to control anxiety  
and diminish recall





**References:** 1. Diazepam and lorazepam in anaesthesia. *Drug Ther Bull* 17(5):19-20, Mar 2, 1979. 2. Conner JT, et al: *J Clin Pharmacol* 18:285-292, May-Jun 1978. 3. George KA, Dundee JW: *Br J Clin Pharmacol* 4:45-50, Feb 1977. 4. Dundee JW, Pandit SK: *Br J Pharmacol* 44:140-144, Jan 1972. 5. Dundee JW, et al: *Br J Anaesth* 51:439-446, May 1979. 6. Gregg JM, Ryan DE, Levin KH: *J Oral Surg* 32:651-664, Sep 1974.

**Injectable Valium® (diazepam/Roche) (V)**  
**Valium® (diazepam/Roche) (V)**

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

**Indications:** Management of anxiety disorders, or short-term relief of symptoms of anxiety. Anxiety or tension associated with the stress of everyday life usually does not require treatment with an anxiolytic. Symptomatic relief of acute agitation, tremor, impending or acute delirium tremens and hallucinosis due to acute alcohol withdrawal; adjunctively in: relief of skeletal muscle spasm due to reflex spasm to local pathology; spasticity caused by upper motor neuron disorders; athetosis; stiff-man syndrome. *Oral form* may be used adjunctively in convulsive disorders, but not as sole therapy. *Injectable form* may also be used adjunctively in: status epilepticus; severe recurrent seizures; tetanus; anxiety, tension or acute stress reactions prior to endoscopic/surgical procedures; cardioversion.

The effectiveness of Valium in long-term use, that is, more than 4 months, has not been assessed by systematic clinical studies. The physician should periodically reassess the usefulness of the drug for the individual patient.

**Contraindications:** Tablets in children under 6 months of age; known hypersensitivity; acute narrow angle glaucoma; may be used in patients with open angle glaucoma who are receiving appropriate therapy.

**Warnings:** As with most CNS-acting drugs, caution against hazardous occupations requiring complete mental alertness (e.g., operating machinery, driving). Withdrawal symptoms similar to those with barbiturates and alcohol have been observed with abrupt discontinuation, usually limited to extended use and excessive doses. Infrequently, milder withdrawal symptoms have been reported following abrupt discontinuation of benzodiazepines after continuous use, generally at higher therapeutic levels, for at least several months. After extended therapy, gradually taper dosage. Keep addiction-prone individuals (drug addicts or alcoholics) under careful surveillance because of predisposition to habituation/dependence.

**Usage in Pregnancy:** Use of minor tranquilizers during first trimester should almost always be avoided because of increased risk of congenital malformations, as suggested in several studies. Consider possibility of pregnancy when instituting therapy; advise patients to discuss therapy if they intend to or do become pregnant.

**ORAL:** Advise patients against simultaneous ingestion of alcohol and other CNS depressants.

Not of value in treatment of psychotic patients; should not be employed in lieu of appropriate treatment. When using oral form adjunctively in convulsive disorders, possibility of increase in frequency and/or severity of grand mal seizures may require increase in dosage of standard anticonvulsant medication; abrupt withdrawal in such cases may be associated with temporary increase in frequency and/or severity of seizures.

**INJECTABLE:** To reduce the possibility of venous thrombosis, phlebitis, local irritation, swelling and, rarely, vascular impairment when used I.V.: Inject slowly, taking at least one minute for each 5 mg (1 ml) given; do not use small veins, i.e., dorsum of hand or wrist; use extreme care to avoid intra-arterial administration or extravasation. Do not mix or dilute Valium with other solutions or drugs in syringe or infusion flask. If it is not feasible to administer Valium directly I.V., it may be injected slowly through the infusion tubing as close as possible to the vein insertion. Administer with extreme care to elderly, very ill, those with limited pulmonary reserve because of possibility of apnea and/or cardiac arrest; concomitant use of barbiturates, alcohol or other CNS depressants increases depression with increased risk of apnea; have resuscitative facilities available. When used with narcotic analgesic eliminate or reduce narcotic dosage at least  $\frac{1}{3}$ , administer in small increments.

**Injectable Valium® (diazepam/Roche)**  
**Valium® (diazepam/Roche)**

Should not be administered to patients in shock, coma, acute alcoholic intoxication with depression of vital signs. Has precipitated tonic status epilepticus in patients treated for petit mal status or petit mal variant status. Not recommended for OB use. Efficacy/safety not established in neonates (age 30 days or less); prolonged CNS depression observed. In children, give slowly (up to 0.25 mg/kg over 3 minutes) to avoid apnea or prolonged somnolence; can be repeated after 15 to 30 minutes. If no relief after third administration, appropriate adjunctive therapy is recommended.

**Precautions:** If combined with other psychotropics or anticonvulsants, carefully consider individual pharmacologic effects—particularly with known compounds which may potentiate action of Valium, i.e., phenothiazines, narcotics, barbiturates, MAO inhibitors and antidepressants. Protective measures indicated in highly anxious patients with accompanying depression who may have suicidal tendencies. Observe usual precautions in impaired hepatic function; avoid accumulation in patients with compromised kidney function. Limit oral dosage to smallest effective amount in elderly and debilitated to preclude ataxia or oversedation (initially 2 to 2½ mg once or twice daily, increasing gradually as needed and tolerated).

The clearance of Valium and certain other benzodiazepines can be delayed in association with Tagamet (cimetidine) administration. The clinical significance of this is unclear.

**INJECTABLE:** Although promptly controlled, seizures may return; readminister if necessary; not recommended for long-term maintenance therapy. Laryngospasm/increased cough reflex are possible during peroral endoscopic procedures; use topical anesthetic, have necessary countermeasures available. Hypotension or muscular weakness possible, particularly when used with narcotics, barbiturates or alcohol. Use lower doses (2 to 5 mg) for elderly/debilitated.

**Adverse Reactions:** Side effects most commonly reported were drowsiness, fatigue, ataxia. Infrequently encountered were confusion, constipation, depression, diplopia, dysarthria, headache, hypotension, incontinence, jaundice, changes in libido, nausea, changes in salivation, skin rash, slurred speech, tremor, urinary retention, vertigo, blurred vision. Paradoxical reactions such as acute hyperexcited states, anxiety, hallucinations, increased muscle spasticity, insomnia, rage, sleep disturbances and stimulation have been reported; should these occur, discontinue drug.

Because of isolated reports of neutropenia and jaundice, periodic blood counts, liver function tests advisable during long-term therapy. Minor changes in EEG patterns, usually low-voltage fast activity, have been observed in patients during and after Valium therapy and are of no known significance.

**INJECTABLE:** Venous thrombosis/phlebitis at injection site, hypoactivity, syncope, bradycardia, cardiovascular collapse, nystagmus, urticaria, hiccups, neutropenia.

In peroral endoscopic procedures, coughing, depressed respiration, dyspnea, hyperventilation, laryngospasm/pain in throat or chest have been reported.

**Management of Overdosage:** Manifestations include somnolence, confusion, coma, diminished reflexes. Monitor respiration, pulse, blood pressure; employ general supportive measures, I.V. fluids, adequate airway. Use levaterenol or metaraminol for hypotension. Dialysis is of limited value.

**How Supplied**

**ORAL:** Round, scored tablets\* with a cut out "V" design—2 mg, white; 5 mg, yellow; 10 mg, blue—bottles of 100 and 500; Prescription Paks of 50, available in trays of 10. Tel-E-Dose® packages of 100, available in boxes of 4 reverse-numbered cards of 25, and in boxes containing 10 strips of 10.

**INJECTABLE:** Ampuls, 2 ml, boxes of 10; Vials, 10 ml, boxes of 1; Tel-E-Ject® (disposable syringes), 2 ml, boxes of 10.

\*Supplied by Roche Products Inc., Manati, Puerto Rico 00701

†Manufactured by Hoffmann-La Roche Inc., distributed by Roche Products Inc.

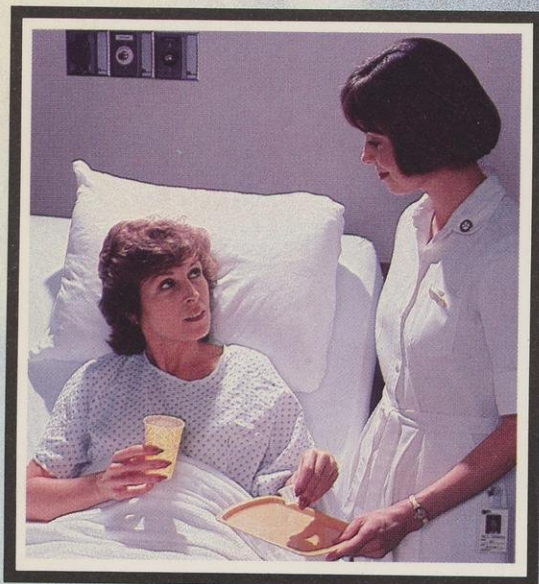




# INVASIVE PROCEDURES...

On the eve of surgery, anxiety can reach excessive levels. At such times, oral Valium (diazepam/Roche) is often especially useful. Its dependable calming action rapidly relieves anxiety—helps assure a more tranquil preoperative night. And Valium is well tolerated by most patients: side effects more serious than fatigue, drowsiness or ataxia are rare.

the night before



Oral  
**VALIUM<sup>®</sup>**  
*diazepam/Roche*

scored tablets



2 mg



5 mg



10 mg

*Note our  
distinctive look*

to control  
mounting anxiety



**MAY DIMINISH  
AFTER THE PROCEDURE  
DIMINISHED RECALL WITH INJECTABLE  
VALIUM (diazepam/Roche) I.V.**

The duration of anterograde amnesia produced by Injectable Valium I.V. parallels the length of most endoscopic procedures. Amnesic effect usually starts within three minutes, peaks within 10 minutes and lasts for 20 to 60 minutes.<sup>6,7</sup> This predictable action can be especially useful in short-term and outpatient procedures.

**NORMALLY DOES NOT COMPROMISE  
RESPIRATORY AND CARDIAC FUNCTION**

When administered at recommended dosage, Injectable Valium rarely causes adverse cardiac or respiratory effects.<sup>5</sup> Resuscitative facilities should be readily available. While Injectable Valium has been used successfully in high-risk and elderly patients,<sup>8-10</sup> caution is advised.

Narcotics administered concomitantly with Injectable Valium I.V. should be reduced by one-third, and in some cases may be omitted. As with most CNS-acting agents, patients receiving Valium should be cautioned against engaging in hazardous occupations requiring complete mental alertness, such as operating machinery or driving a motor vehicle.

Rapid and predictable action with a proven record of safety. That is why so many endoscopic procedures start with Injectable Valium I.V.

**RAPID AND  
PREDICTABLE  
CALMING  
ACTION WITH  
INJECTABLE  
VALIUM® I.V.  
diazepam/Roche ©**

2-ml disposable syringes } 5 mg/ml  
2-ml ampuls, 10-ml vials }

Please see following page for references and a summary of product information.

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**References:** 1. Thompson DG *et al*: *Lancet* 2:469-470, Aug 30, 1980. 2. Diazepam and lorazepam in anaesthesia. *Drug Ther Bull* 17(5): 19-20, Mar 2, 1979. 3. Conner JT *et al*: *J Clin Pharmacol* 18:285-292, May-Jun 1978. 4. Ludlam R, Bennett JR: *Lancet* 2:1397-1399, Dec 25, 1971. 5. Data on file, Hoffmann-La Roche Inc., Nutley, NJ.



6. George KA, Dundee JW: *Br J Clin Pharmacol* 4:45-50, Feb 1977. 7. Dundee JW, Pandit SK: *Br J Pharmacol* 44:140-144, Jan 1972. 8. Greenblatt DJ, Koch-Weser J: *Am J Med Sci* 266:261-266, Oct 1973. 9. Jacobsohn WZ, Levy A: *Geriatrics* 32(1):80-83, Jan 1977. 10. Sherr HP, Cocco AE: *Am J Med Sci* 267:151-158, Mar 1974.

# INJECTABLE VALIUM® (diazepam/Roche) IV

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

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**Contraindications:** Hypersensitivity; acute narrow angle glaucoma; may be used in patients with open angle glaucoma receiving appropriate therapy.

**Warnings:** To reduce the possibility of venous thrombosis, phlebitis, local irritation, swelling, and, rarely, vascular impairment when used I.V.: inject slowly, taking at least one minute for each 5 mg (1 ml) given; do not use small veins, i.e., dorsum of hand or wrist; use extreme care to avoid intra-arterial administration or extravasation. Do not mix or dilute Valium with other solutions or drugs in syringe or infusion flask. If it is not feasible to administer Valium directly I.V., it may be injected slowly through the infusion tubing as close as possible to the vein insertion.

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Not recommended for OB use.

Efficacy/safety not established in neonates (age 30 days or less); prolonged CNS depression observed. In children, give slowly (up to 0.25 mg/kg over 3 minutes) to avoid apnea or prolonged somnolence; can be repeated after 15 to 30 minutes. If no relief after third administration, appropriate adjunctive therapy is recommended.

**Precautions:** Although promptly controlled, seizures may return; re-administer if necessary; not recommended for long-term maintenance therapy. If combined with other psychotropics or anticonvulsants, carefully consider individual pharmacologic effects—particularly with known compounds which may potentiate action of Valium (diazepam/Roche), i.e., phenothiazines, narcotics, barbiturates, MAO inhibitors, antidepressants. Protective measures indicated in highly anxious patients with accompanying depression who may have suicidal tendencies. Observe usual precautions in impaired hepatic function; avoid accumulation in patients with compromised kidney function. Laryngospasm/increased cough reflex are possible during peroral endoscopic procedures; use topical anesthetic, have necessary countermeasures available. Hypotension or muscular weakness possible, particularly when used with narcotics, barbiturates or alcohol. Use lower doses (2 to 5 mg) for elderly/debilitated.

The clearance of Valium and certain other benzodiazepines can be delayed in association with Tagamet (cimetidine) administration. The clinical significance of this is unclear.

**Adverse Reactions:** Drowsiness, fatigue, ataxia, venous thrombosis/phlebitis at injection site, confusion, depression, dysarthria, headache, hypoactivity, slurred speech, syncope, tremor, vertigo, constipation, nausea, incontinence, changes in libido, urinary retention, bradycardia, cardiovascular collapse, hypotension, blurred vision, diplopia, nystagmus, urticaria, skin rash, hiccups, changes in salivation, neutropenia, jaundice. Paradoxical reactions such as acute hyperexcited states, anxiety, hallucinations, increased muscle spasticity, insomnia, rage, sleep disturbances, stimulation have been reported; should these occur, discontinue drug. Cough, depressed respiration, dyspnea, hyperventilation, laryngospasm/pain in throat and chest have been reported in peroral endoscopic procedures. Isolated reports of neutropenia, jaundice; periodic blood counts, liver function tests advisable during long-term therapy. Minor EEG changes, usually low-voltage fast activity, of no known significance.

**Dosage:** Usual initial dose in older children and adults is 2 to 20 mg I.M. or I.V., depending on indication and severity. Larger doses may be required in some conditions (tetanus). In acute conditions injection may be repeated within 1 hour, although interval of 3 to 4 hours is usually satisfactory. Lower doses (usually 2 to 5 mg) with slow dosage increase for elderly or debilitated patients and when sedative drugs are added. (See Warnings and Adverse Reactions.)

For dosages in infants and children see below; have resuscitative facilities available.

**I.M. use:** by deep injection into the muscle.

**I.V. use:** inject slowly, take at least one minute for each 5 mg (1 ml) given. Do not use small veins, i.e., dorsum of hand or wrist. Use extreme care to avoid intra-arterial administration or extravasation. Do not mix or dilute Valium with other solutions or drugs in syringe or infusion flask. If it is not feasible to administer Valium directly I.V., it may be injected slowly through the infusion tubing as close as possible to the vein insertion.

Moderate anxiety disorders and symptoms of anxiety, 2 to 5 mg I.M. or I.V. and severe anxiety disorders and symptoms of anxiety, 5 to 10 mg I.M. or I.V., repeat in 3 to 4 hours if necessary; acute alcohol withdrawal, 10 mg I.M. or I.V. initially, then 5 to 10 mg in 3 to 4 hours if necessary. Muscle spasm, in adults, 5 to 10 mg I.M. or I.V. initially, then 5 to 10 mg in 3 to 4 hours if necessary (tetanus may require larger doses); in children, administer I.V. slowly; for tetanus in infants over 30 days of age, 1 to 2 mg I.M. or I.V., repeat every 3 to 4 hours if necessary; in children 5 years or older, 5 to 10 mg repeated every 3 to 4 hours as needed. Respiratory assistance should be available.

Status epilepticus, severe recurrent convulsive seizures (I.V. route preferred), 5 to 10 mg adult dose administered slowly, repeat at 10- to 15-minute intervals up to 30 mg maximum. Repeat in 2 to 4 hours if necessary keeping in mind possibility of residual active metabolites. Use caution in presence of chronic lung disease or unstable cardiovascular status. Infants (over 30 days) and children (under 5 years), 0.2 to 0.5 mg slowly every 2 to 5 min., up to 5 mg (I.V. preferred). Children 5 years plus, 1 mg every 2 to 5 min., up to 10 mg (slow I.V. preferred); repeat in 2 to 4 hours if needed. EEG monitoring may be helpful.

In endoscopic procedures, titrate I.V. dosage to desired sedative response, generally 10 mg or less but up to 20 mg (if narcotics are omitted) immediately prior to procedure; if I.V. cannot be used, 5 to 10 mg I.M. approximately 30 minutes prior to procedure. As preoperative medication, 10 mg I.M.; in cardioversion, 5 to 15 mg I.V. within 5 to 10 minutes prior to procedure. Once acute symptomatology has been properly controlled with injectable form, patient may be placed on oral form if further treatment is required.

**Management of Overdosage:** Manifestations include somnolence, confusion, coma, diminished reflexes. Monitor respiration, pulse, blood pressure; employ general supportive measures, I.V. fluids, adequate airway. Hypotension may be combated by the use of levarterenol or metaraminol. Dialysis is of limited value.

**Supplied:** Ampuls, 2 ml, boxes of 10; Vials, 10 ml, boxes of 1; Tel-E-Ject® (disposable syringes), 2 ml, boxes of 10. Each ml contains 5 mg diazepam compounded with 40% propylene glycol, 10% ethyl alcohol, 5% sodium benzoate and benzoic acid as buffers, and 1.5% benzyl alcohol as preservative.



Manufactured by Hoffmann-La Roche Inc.  
Nutley, New Jersey 07110  
Distributed by Roche Products Inc.  
Manati, Puerto Rico 00701



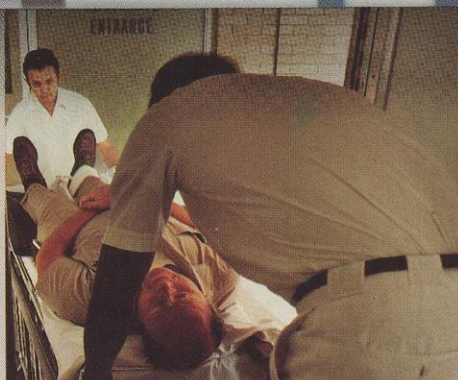
# No other choice is as versatile...

VALIUM® 10 mg  
diazepam/Roche® <sup>IV</sup>

2 ml (10 mg)

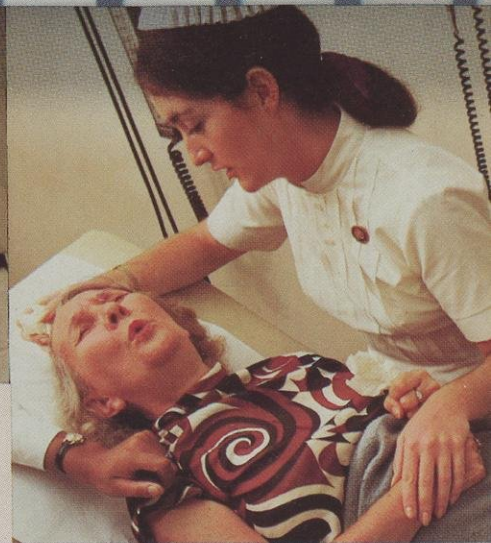
1.5

1 ml (5 mg)



In the OPD and ER

For elderly as well as young  
patients in office or hospital



**Predictable onset of action**—within 1-3 minutes after I.V. administration patients become relaxed, yet remain able to follow directions. Reconstitution is not necessary; Injectable Valium (diazepam/Roche) is ready for immediate use. (For complete administration guidelines, precautions and standby equipment, see complete product information.)

**Predictable duration of clinical effects**—I.V. administration produces anterograde amnesia of short duration, usually 20 to 60 minutes. And drowsiness fades within a few hours of surgery. This is in sharp contrast to agents whose effects may last up to 8 hours or longer. (As with all parenteral tranquilizers, patients should be cautioned against hazardous occupations requiring complete mental alertness, such as operating machinery or driving.)