treatment for psychotic or severely depressed patients. Injectable Valium (diazepam) should not be administered to patients in shock, coma, or in acute alcoholic intoxication with depression of vital signs.

Physical and Psychological Dependence: Withdrawal symptoms (similar in character to those noted with barbiturates and alcohol) have occurred following abrupt discontinuance of diazepam (convulsions, tremor, abdominal and muscle cramps, vomiting and sweating). These were usually limited to those patients who had received excessive doses over an extended period of time. Particularly addiction-prone individuals (such as drug addicts or alcoholics) should be under careful surveillance when receiving diazepam or other psychotropic agents because of the predisposition of such patients to habituation and dependence.

Use in Pregnancy: Use of any drug in pregnancy, lactation or in women of childbearing age requires that the potential benefit of the drug be weighed against its possible hazard to mother and child. (See *Reproduction Studies.*)

Management of Overdosage: Manifestations of Valium (diazepam) overdosage include somnolence, confusion, coma and diminished reflexes. Respiration, pulse and blood pressure should be monitored, as in all cases of drug overdosage, although, in general, these effects have been minimal following overdosage. General supportive measures should be employed, along with immediate gastric lavage. Intravenous fluids should be administered and an adequate airway maintained. Hypotension may be combated by the use of Levophed® (levarterenol) or Aramine (metaraminol). Ritalin (methylphenidate) or caffeine and sodium benzoate may be given to combat CNS-depressive effects. Dialysis is of limited value. As with the management of intentional overdosage with any drug, it should be borne in mind that multiple agents may have been ingested.

Precautions: ORAL AND INJECTABLE: If Valium (diazepam) is to be combined with other psychotropic agents or anticonvulsant drugs, careful consideration should be given to the pharmacology of the agents to be employed—particularly with known compounds which may potentiate the action of Valium (diazepam), such as phenothiazines, narcotics, barbiturates, MAO inhibitors and other antidepressants. The usual precautions are indicated for severely depressed patients or those in whom there is any evidence of latent depression; particularly the recognition that suicidal tendencies may be present and protective measures may be necessary. The usual precautions in treating patients with impaired renal or hepatic function should be observed.

ORAL: In elderly and debilitated patients, it is recommended that the dosage be limited to the smallest effective amount to preclude the development of ataxia or oversedation (2 mg to 2½ mg once or twice daily, initially, to be increased gradually as needed and tolerated).

INJECTABLE: Valium (diazepam) is not recommended for bronchoscopy and laryngoscopy, because increased cough reflex and laryngospasm have been reported. Furthermore, during gastroscopy the operator must be aware of this possible reaction and necessary countermeasures should be available. Until additional information on its safety and efficacy is available, injectable diazepam is not recommended for obstetrical use or in diagnostic procedures other than gastroscopy and esophagoscopy.

Injectable Valium (diazepam) has produced hypotension, respiratory depression or muscular weakness in some patients, particularly when used with narcotics, barbiturates or alcohol. Since Valium (diazepam) may have an additive effect with narcotics, appropriate reduction in narcotic dosage is possible.
Lower doses (usually 2 mg to 5 mg) should be used for elderly and debilitated patients.

The safety and efficacy of Injectable Valium (diazepam) in children under age 12 have not been established.

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

ORAL: Side effects most commonly reported were drowsiness, fatigue and 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 and 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, use of the drug should be discontinued.

INJECTABLE: Side effects most commonly reported were drowsiness, fatigue and ataxia. Infrequently encountered were confusion, constipation, depression, diplopia, dysarthria, headache, hiccups, hypoactivity, hypotension, incontinence, jaundice, changes in libido, nausea, phlebitis at injection site, changes in salivation, skin rash, slurred speech, syncope, tremor, urinary retention, urticaria, vertigo and 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, use of the drug should be discontinued.

Dosage and Administration: ORAL: Dosage should be individualized for maximum beneficial effect. While the usual daily dosages given below will meet the needs of most patients, there will be some who may require higher doses. In such cases dosage should be increased cautiously to avoid adverse effects.

Adults:	**Usual daily dose**
Symptomatic Relief of Tension and Anxiety States and Psychoneurotic States.	Depending upon severity of symptoms—2 mg to 10 mg, 2 to 4 times daily
Symptomatic Relief in Acute Alcohol Withdrawal.	10 mg, 3 or 4 times during the first 24 hours, reducing to 5 mg, 3 or 4 times daily as needed
Adjunctively for Relief of Skeletal Muscle Spasm.	2 mg to 10 mg, 3 or 4 times daily
Adjunctively in Convulsive Disorders.	2 mg to 10 mg, 2 to 4 times daily
Geriatric Patients, or in the presence of debilitating disease.	2 mg to 2½ mg, 1 or 2 times daily initially; increase gradually as needed and tolerated
Children: Because of varied responses to CNS-acting drugs, initiate therapy with lowest dose and increase as required. Not for use in children under 6 months.	1 mg to 2½ mg, 3 or 4 times daily initially; increase gradually as needed and tolerated

Dosage and Administration: INJECTABLE: Dosage should be individualized for maximum beneficial effect. In acute conditions the injection may be repeated within one hour although an interval of 3 to 4 hours is usually satisfactory. Generally not more than 30 mg should be given within an 8-hour period.

Intramuscular: Injectable Valium (diazepam) should be injected deeply into the muscle.

Intravenous use: The solution should be injected slowly, directly into the vein, taking at least one minute for each 5 mg (1 cc) given. Do not mix or dilute Injectable Valium (diazepam) with other solutions or drugs. Do not add to I.V. fluids.

	Usual dosage*
Moderate Psychoneurotic Reactions: Manifested by tension-anxiety alone or with depressive symptomatology, agitation, restlessness and psychophysiological disturbances.	2 mg to 5 mg, I.M. or I.V. Repeat in 3 to 4 hours, if necessary.
Severe Psychoneurotic Reactions: Where severe anxiety, apprehension or agitation exist alone or associated with depressive symptoms.	5 mg to 10 mg, I.M. or I.V. Repeat in 3 to 4 hours, if necessary.
Acute Alcohol Withdrawal: As an aid in symptomatic relief of acute agitation, tremor, impending or acute delirium tremens and hallucinosis.	10 mg, I.M. or I.V. initially, then 5 mg to 10 mg in 3 to 4 hours, if necessary.
Acute Stress Reactions: Adjunctively, when apprehension, anxiety and acute stress reactions are present prior to gastroscopy and esophagoscopy. (See **Precautions.**)	5 mg to 10 mg, I.M. or I.V., approximately 30 minutes prior to the procedure.
Muscle Spasm: Associated with local pathology, cerebral palsy, athetosis, stiff-man syndrome or tetanus.	5 mg to 10 mg, I.M. or I.V. initially, then 5 mg to 10 mg in 3 to 4 hours, if necessary. For tetanus, larger doses may be required.
Status Epilepticus and Severe Recurrent Convulsive Seizures: In the convulsing patient, it is recommended the drug be given intramuscularly if there is difficulty in administering it slowly intravenously over the required period of time.	5 mg to 10 mg, I.M. or I.V. initially. Repeat in 2 to 4 hours, if necessary.
Preoperative Medication: To relieve anxiety and tension. *(If atropine, scopolamine or other premedication are desired, they must be administered in separate syringes.)*	10 mg, I.M. (preferred route), 1 to 2 hours before surgery.
Cardioversion: To relieve anxiety and tension.	5 mg to 15 mg, I.V., within 5 to 10 minutes prior to the procedure.

*Lower doses (usually 2 mg to 5 mg) and slow increase in dosage should be used for elderly or debilitated patients and when other sedative drugs are administered. (See **Precautions** and **Adverse Reactions.**)

Once the acute symptomatology has been properly controlled with Injectable Valium (diazepam), the patient may be placed on oral therapy with Valium (diazepam) if further treatment is required.

How Supplied: ORAL: Valium (diazepam) scored tablets—2 mg, white; 5 mg, yellow; and 10 mg, blue—bottles of 100 and 500.

INJECTABLE: Ampuls, 2 cc, boxes of 10. Each cc 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.