

Valium (diazepam)

Tablets 2 mg,
5 mg, 10 mg
Ampuls 2 cc

By relieving psychic tension, it
can help

- ☐ ease patients into therapy
- ☐ lessen reaction to crisis situations
- ☐ improve communication
- ☐ reduce tension-induced insomnia and fatigue
- ☐ relieve stress-induced psychosomatic symptoms
- ☐ support the patient between therapeutic sessions

Complete Prescribing Information

Description: (Oral and Injectable) Valium (diazepam) is a benzodiazepine derivative developed through original Roche research. Chemically, diazepam is 7-chloro-1,3-dihydro-1-methyl-5-phenyl-2H-1,4-benzodiazepin-2-one. It is a colorless crystalline compound, insoluble in water and has a molecular weight of 284.74.

Pharmacology: (Oral and Injectable) In animals Valium (diazepam) appears to act on parts of the limbic system, the thalamus and hypothalamus, and induces calming effects. Valium (diazepam), unlike chlorpromazine and reserpine, has no demonstrable peripheral autonomic blocking action, nor does it produce extrapyramidal side effects; however, animals treated with Valium (diazepam) do have a transient startle at higher doses. Valium (diazepam) was found to have transient cardiovascular depressor effects in dogs. Long-term experiments in rats revealed no disturbances of endocrine function. Injections into animals have produced localized irritation of tissue surrounding injection sites and some thickening of veins after intravenous use.

Oral LD₅₀ of diazepam is 720 mg/kg in mice and 1240 mg/kg in rats. Intraperitoneal administration of 400 mg/kg to a monkey resulted in death on the sixth day.

Reproduction Studies: A series of rat reproduction studies was performed with diazepam in oral doses of 1, 10, 80 and 100 mg/kg. At 100 mg/kg there was a decrease in the number of pregnancies and surviving offspring in these rats. Neonatal survival of rats at doses lower than 100 mg/kg was within normal limits. Several neonates in these rat reproduction studies showed skeletal or other defects. Further studies in rats at doses up to and including 80 mg/kg/day did not reveal teratological effects on the offspring.

In humans, measurable blood levels of Valium (diazepam) were obtained in maternal and cord blood, indicating placental transfer of the drug.

Indications: ORAL AND INJECTABLE: Valium (diazepam) is useful in the symptomatic relief of tension and anxiety states resulting from stressful circumstances or whenever somatic complaints are concomitants of emotional factors. It is useful in psychoneurotic states manifested by tension, anxiety, apprehension, fatigue, depressive symptoms or agitation.

In acute alcohol withdrawal, Valium (diazepam) may be useful in the symptomatic relief of acute agitation, tremor, impending or acute delirium tremens and hallucinosis.

Valium (diazepam) is a useful adjunct for the relief of skeletal muscle spasm due to reflex spasm to local pathology (such as inflammation of the muscles or joints, or secondary to trauma); spasticity caused by upper motor neuron disorders (such as cerebral palsy and paraplegia); athetosis; stiff-man syndrome.

ORAL: Oral Valium (diazepam) may be used adjunctively in convulsive disorders, although it has not proved useful as the sole therapy.

INJECTABLE: Tetanus. If apprehension, anxiety and acute stress reactions are present prior to gastroscopy and esophagoscopy, injectable Valium (diazepam) may be a valuable adjunct. (See Precautions.)

Injectable Valium (diazepam) is a useful adjunct in status epilepticus and severe recurrent convulsive seizures.

Valium (diazepam) is a useful premedication (the I.M. route is preferred) for relief of anxiety and tension in patients who are to undergo surgical procedures. Intravenously, it is also useful prior to cardioversion. In either instance, the patient's recall of the procedure is markedly diminished.

Contraindications: ORAL: Valium (diazepam) is contraindicated in patients with a known hypersensitivity to this drug and, because of lack of sufficient clinical experience, in children under 6 months of age. It may be used in patients with open angle glaucoma who are receiving appropriate therapy, but is contraindicated in acute narrow angle glaucoma.

INJECTABLE: Injectable Valium (diazepam) is contraindicated in infants and in patients with a known hypersensitivity to this drug. It may be used in patients with open angle glaucoma who are receiving appropriate therapy, but is contraindicated in acute narrow angle glaucoma.

Warnings: ORAL AND INJECTABLE: As is true of most CNS-acting drugs, patients receiving Valium (diazepam) should be cautioned against engaging in hazardous occupations requiring complete mental alertness, such as operating machinery or driving a motor vehicle.

Since Valium (diazepam) has a central nervous system depressant effect, patients should be advised against the simultaneous ingestion of alcohol and other CNS-depressant drugs during Valium (diazepam) therapy.

ORAL: Valium (diazepam) is not of value in the treatment of psychotic patients and should not be employed in lieu of appropriate treatment. As with other agents which have anticonvulsant activity, when Valium (diazepam) is used as an adjunct in treating convulsive disorders, the possibility of an increase in the frequency and/or severity of grand mal seizures may require an increase in the dosage of standard anticonvulsant medication. Abrupt withdrawal of Valium (diazepam) in such cases may also be associated with a temporary increase in the frequency and/or severity of seizures.

INJECTABLE: When used intravenously 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. Injectable Valium (diazepam) is not recommended as the sole