# Valium (diazepam) - Drug Summary

Genentech, Inc.





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## Valium (diazepam)

## THERAPEUTIC CLASS

Benzodiazepine

## DEA CLASS

CIV

## ADULT DOSAGE & INDICATIONS

### Anxiety Disorders

**Management of Disorders or for Short-Term Relief of Symptoms:**
2-10mg bid-qid

### Alcohol Withdrawal

**Symptomatic Relief of Acute Withdrawal:**
10mg tid or qid for first 24 hrs, then reduce to 5mg tid or qid prn

### Muscle Spasms

**Adjunctive Therapy:**
2-10mg tid or qid

### Convulsive Disorders

**Adjunctive Therapy:**
2-10mg bid-qid

## PEDIATRIC DOSAGE & INDICATIONS

### General Dosing

**≥6 Months of Age:**
**Initial:** 1-2.5mg tid or qid
**Titrate:** Increase gradually prn and as tolerated

## DOSING CONSIDERATIONS

**Elderly**
**Elderly/Debilitated:**
**Initial:** 2-2.5mg qd or bid
**Titrate:** Increase gradually prn and as tolerated

## ADMINISTRATION

Oral route

## HOW SUPPLIED

Tab: 2mg*, 5mg*, 10mg* *scored

## CONTRAINDICATIONS

Known hypersensitivity to diazepam, pediatric patients <6 months of age, myasthenia gravis, severe respiratory insufficiency, severe hepatic insufficiency, sleep apnea syndrome, acute narrow-angle glaucoma.

## WARNINGS/PRECAUTIONS

May be used with treated open-angle glaucoma. Periodically reassess usefulness of drug. Not recommended for the treatment of psychotic patients. May increase frequency and/or severity of grand mal seizures and may require an increase in the dose of standard anticonvulsant medication. Abrupt withdrawal may also temporarily increase frequency and/or severity of seizures. May increase risk of congenital malformations and other developmental abnormalities. Caution during labor and delivery. Caution in the severely depressed or with evidence of latent depression or anxiety associated with depression, or suicidal tendencies; protective measures may be necessary. Psychiatric and paradoxical reactions may occur and are more likely in children and the elderly; d/c if these occur. Lower dose is recommended with chronic respiratory insufficiency. Extreme caution with history of alcohol or drug abuse. In debilitated patients, limit dose to smallest effective amount to preclude ataxia or oversedation development. Repeated use for a prolonged time may result in some loss of response to effects. Isolated reports of neutropenia and jaundice reported. Abuse and dependence reported.

## ADVERSE REACTIONS

Drowsiness, fatigue, muscle weakness, ataxia.

## DRUG INTERACTIONS

Mutually potentiates effects with central acting agents (eg, antipsychotics, anxiolytics/sedatives, MAOIs). Alcohol enhances sedative effects; avoid concomitant use. Slower rate of absorption with antacids. Concomitant use with compounds which inhibit certain hepatic enzymes such as CYP3A and CYP2C19 (eg, cimetidine, ketoconazole, fluvoxamine) may increase and prolong sedation. Decreased metabolic elimination of phenytoin reported.

## PREGNANCY AND LACTATION

Category D, not for use in nursing.

## MECHANISM OF ACTION

Benzodiazepine; exerts anxiolytic, sedative, muscle-relaxant, anticonvulsant, and amnestic effects. Thought to facilitate action of gamma aminobutyric acid, an inhibitory neurotransmitter in the CNS.

## PHARMACOKINETICS

**Absorption:** $T_{max}$=1-1.5 hrs. **Distribution:** $V_d$=0.8-1.0L/kg; plasma protein binding (98%); crosses placenta, found in breast milk. **Metabolism:** N-demethylation via CYP3A4/2C19, hydroxylation via CYP3A4, glucuronidation; N-desmethyldiazepam and temazepam (active metabolites). **Elimination:** Urine (glucuronide conjugates); $T_{1/2}$≤48 hrs, ≤100 hrs (N-desmethyldiazepam).

## ASSESSMENT

Assess for hypersensitivity to drug, acute narrow-angle glaucoma, myasthenia gravis, severe respiratory/hepatic insufficiency, sleep apnea syndrome, history of seizures, psychosis, depression, history of alcohol/drug abuse, debilitation, pregnancy/nursing status, and possible drug interactions.

## MONITORING

Monitor for hypersensitivity reactions, withdrawal symptoms, seizures, psychiatric/paradoxical reactions, respiratory depression, loss of response during prolonged use, abuse, dependence, and other adverse reactions. Monitor CBC and LFTs periodically during long-term therapy.

## PATIENT COUNSELING

Inform of potential hazard to the fetus during pregnancy; advise to notify physician if nursing, pregnant, or intending to become pregnant during therapy. Inform that medication may produce psychological and physical dependence especially with history of alcohol/drug abuse; advise to consult physician before increasing dose or abruptly discontinuing the drug. Advise against simultaneous ingestion of alcohol and other CNS depressants during therapy. Caution against engaging in hazardous occupations requiring complete mental alertness (eg, operating machinery, driving).

## STORAGE

15-30°C (59-86°F).

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