Diazepam Oral Solution/Intensol Oral Solution (diazepam) - Drug Summary

Roxane Laboratories, Inc.

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Diazepam Solution (diazepam)

THERAPEUTIC CLASS

Benzodiazepine

DEA CLASS

CIV

ADULT DOSAGE & INDICATIONS

Anxiety Disorders

Management of Anxiety Disorders or for Short-Term Relief of Anxiety Symptoms:
Usual: 2-10mg bid-qid, depending upon severity of symptoms

Alcohol Withdrawal

Symptomatic Relief of Acute Withdrawal:
Usual: 10mg 3X or 4X during the first 24 hrs, and then reduce to 5mg tid or qid prn

Muscle Spasms

Adjunct for the relief of skeletal muscle spasm due to reflex spasm to local pathology (eg, inflammation of muscles or joints, or secondary to trauma); spasticity caused by upper motor neuron disorders (eg, cerebral palsy, paraplegia); athetosis; and stiff-man syndrome

Usual: 2-10mg tid or qid

Convulsive Disorders

Adjunctive Therapy:
Usual: 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/Debilitated
Initial: 2-2.5mg qd or bid
Titrate: Increase gradually prn and as tolerated

ADMINISTRATION

Oral route

Intensol
Mix w/ liquid or semi-solid food (eg, water, juices, soda/soda-like beverages, applesauce, puddings); entire amount of mixture immediately should be consumed
Use only calibrated dropper provided

HOW SUPPLIED

Sol: 5mg/5mL [500mL], (Intensol) 5mg/mL [30mL]

CONTRAINDICATIONS

Known hypersensitivity to this drug, acute narrow-angle glaucoma, and children <6 months of age.

WARNINGS/PRECAUTIONS

May be used in patients with open-angle glaucoma who are receiving appropriate therapy. Not of value in the treatment of psychotic patients and should not be employed in lieu of appropriate treatment. May impair mental/physical abilities. When used as adjunct in treating convulsive disorders, may increase frequency and/or severity of grand mal seizures, which may require an increase in the dosage of standard anticonvulsant medication; abrupt withdrawal may also temporarily increase frequency and/or severity of seizures. May increase risk of congenital malformations if used during the 1st trimester of pregnancy. Withdrawal symptoms of the barbiturate-type may occur; avoid abrupt discontinuation after extended therapy. Caution with severe depression, latent depression, renal/hepatic impairment, and in elderly/debilitated patients.

ADVERSE REACTIONS

Drowsiness, fatigue, ataxia.

DRUG INTERACTIONS

Avoid simultaneous ingestion of alcohol and other CNS-depressant drugs during therapy. Caution with other psychotropic agents or anticonvulsants, particularly with compounds that may potentiate the action of diazepam (eg, phenothiazines, narcotics, barbiturates, MAOIs, and other antidepressants). Cimetidine may delay clearance.

PREGNANCY AND LACTATION

Avoid during the 1st trimester of pregnancy; safety not known in nursing.

MECHANISM OF ACTION

Benzodiazepine; appears to act on parts of the limbic system, the thalamus and hypothalamus, and induces calming effects (animal study).

PHARMACOKINETICS

Distribution: Crosses the placenta.

ASSESSMENT

Assess for drug hypersensitivity, acute narrow-angle glaucoma, depression, renal/hepatic impairment, debilitation, drug/alcohol addiction, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for increased frequency/severity of seizures, withdrawal symptoms, and other adverse reactions. Perform periodic blood counts and LFTs during long-term therapy. Periodically reassess usefulness of drug.

PATIENT COUNSELING

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

STORAGE

25°C (77°F); excursions permitted to 15-30°C (59-86°F). (Intensol) Protect from light. Discard opened bottle after 90 days.

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