Librium (chlordiazepoxide hydrochloride) - Drug Summary

Valeant Pharmaceuticals North America LLC

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Librium (chlordiazepoxide hydrochloride)

THERAPEUTIC CLASS

Benzodiazepine

DEA CLASS

CIV

ADULT DOSAGE & INDICATIONS

Anxiety Disorders

Management of anxiety disorders or for short-term relief of anxiety symptoms

Relief of Mild and Moderate Anxiety Disorders and Symptoms of Anxiety:
Usual: 5-10mg tid-qid

Relief of Severe Anxiety Disorders and Symptoms of Anxiety:
Usual: 20-25mg tid-qid

Preoperative Medication

Preoperative Apprehension and Anxiety:
5-10mg tid-qid on days preceding surgery
If used as preoperative medication, 50-100mg IM 1 hr prior to surgery

Alcohol Withdrawal

Relief of Withdrawal Symptoms of Acute Alcoholism:
Initial: 50-100mg, followed by repeated doses prn until agitation is controlled
Max: 300mg/day

PEDIATRIC DOSAGE & INDICATIONS

Anxiety Disorders

Management of anxiety disorders or for short-term relief of anxiety symptoms

≥6 Years:
Usual: 5mg bid-qid; may increase to 10mg bid-tid in some patients

DOSING CONSIDERATIONS

Elderly
Elderly/Debilitated:
Usual: 5mg bid-qid

ADMINISTRATION

Oral route

HOW SUPPLIED

Cap: 5mg, 10mg, 25mg

WARNINGS/PRECAUTIONS

May impair mental/physical abilities, including mental alertness in children. Risk of congenital malformations during 1st trimester of pregnancy; avoid use. Paradoxical reactions (eg, excitement, stimulation, and acute rage)

reported in psychiatric patients, and in hyperactive aggressive pediatric patients. Caution in treatment of anxiety states with evidence of impending depression; suicidal tendencies may be present. Caution with porphyria, renal or hepatic dysfunction. Use lowest effective dose in elderly and debilitated patients. Avoid abrupt withdrawal after extended therapy; withdrawal symptoms reported following discontinuation.

ADVERSE REACTIONS

Drowsiness, ataxia, confusion, skin eruptions, edema, nausea, constipation, extrapyramidal symptoms, libido changes, EEG changes.

DRUG INTERACTIONS

Additive effects with CNS depressants and alcohol. Coadministration with other psychotropic agents not recommended; caution with MAOIs and phenothiazines. Altered coagulation effects reported with oral anticoagulants.

PREGNANCY AND LACTATION

Not for use in pregnancy, safety not known in nursing.

MECHANISM OF ACTION

Benzodiazepine; not established. Has antianxiety, sedative, appetite stimulating, and weak analgesic actions; blocks EEG arousal from stimulation of brain stem reticular formation.

PHARMACOKINETICS

Elimination: Urine (1-2% unchanged, 3-6% conjugates); $T_{1/2}$=24-48 hrs.

ASSESSMENT

Assess for pregnancy status, hepatic/renal function, and possible drug interactions.

MONITORING

Monitor elderly/debilitated patients for ataxia and oversedation, drowsiness, confusion. Monitor for paradoxical reactions in psychiatric patients and in hyperactive aggressive pediatric patients. Periodic blood counts and LFTs are advisable when treatment is protracted. Monitor for signs of impending depression or any suicidal tendencies.

PATIENT COUNSELING

Inform that psychological/physical dependence may occur; advise to consult physician prior to increasing dose or abruptly discontinuing therapy. Advise to notify physician if patient becomes pregnant or plans to become pregnant. May impair mental/physical abilities; caution while operating machinery/driving. May impair mental alertness in children. Avoid alcohol and other CNS depressant drugs.

STORAGE

25°C (77°F); excursions permitted to 15-30°C (59-86°F).

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