Lorazepam Intensol Oral Concentrate (lorazepam) - Drug Summary

Roxane Laboratories, Inc.

Related Drug Information ▼

Lorazepam Oral (lorazepam)

COMMON BRAND NAMES

Ativan, Lorazepam Oral

THERAPEUTIC CLASS

Benzodiazepine

DEA CLASS

CIV

ADULT DOSAGE & INDICATIONS

Anxiety Disorders

Anxiety Disorders or Short-Term Relief of Symptoms of Anxiety or Anxiety Associated w/ Depressive Symptoms:
Initial: 2-3mg/day given bid or tid
Usual: 2-6mg/day in divided doses; take largest dose before hs
Dosage Range: 1-10mg/day

Increase dose gradually prn; when higher dosage is indicated, increase pm dose before daytime doses

Insomnia Due to Anxiety or Transient Situational Stress:
2-4mg as a single daily dose qhs

PEDIATRIC DOSAGE & INDICATIONS

Anxiety Disorders

Anxiety Disorders or Short-Term Relief of Symptoms of Anxiety or Anxiety Associated w/ Depressive Symptoms:
≥12 Years:
Initial: 2-3mg/day given bid or tid
Usual: 2-6mg/day in divided doses; take largest dose before hs
Dosage Range: 1-10mg/day

Increase dose gradually prn; when higher dosage is indicated, increase pm dose before daytime doses

Insomnia Due to Anxiety or Transient Situational Stress:
2-4mg as a single daily dose qhs

DOSING CONSIDERATIONS

Elderly
Elderly/Debilitated:
Initial: 1-2mg/day in divided doses; adjust prn and as tolerated

ADMINISTRATION

Oral route

Sol
Dispense only in the bottle and only w/ the calibrated dropper provided
Mix w/ liquid or semi-solid food for a few sec; Intensol formulation blends quickly and completely
Entire amount of mixture, of drug and liquid or drug and food, should be consumed immediately

HOW SUPPLIED

Sol: 2mg/mL; Tab: (Ativan) 0.5mg, 1mg*, 2mg* *scored

CONTRAINDICATIONS

Hypersensitivity to benzodiazepines or to any components of the formulation, acute narrow-angle glaucoma.

WARNINGS/PRECAUTIONS

Effectiveness in long-term use (>4 months) has not been assessed; prescribe for short periods only (eg, 2-4 weeks) and periodically reassess usefulness of drug. Continuous long-term use is not recommended. Preexisting depression may emerge or worsen; not for use with primary depressive disorder or psychosis. May lead to potentially fatal respiratory depression. May impair mental/physical abilities. Use may lead to physical and psychological dependence; increased risk with higher doses, longer term use, and in patients with history of alcoholism/drug abuse, or with significant personality disorders. Withdrawal symptoms reported; avoid abrupt d/c and follow a gradual dosage-tapering schedule after extended therapy. May develop tolerance to sedative effects. Paradoxical reactions reported; d/c if these occur. May have abuse potential, especially with a history of drug and/or alcohol abuse. Possible suicide in patients with depression; do not use in such patients without adequate antidepressant therapy. Caution with compromised respiratory function (eg, COPD, sleep apnea syndrome), impaired renal/hepatic function, hepatic encephalopathy, in elderly, and in debilitated patients. May worsen hepatic encephalopathy. Adjust dose with severe hepatic insufficiency; lower doses may be sufficient. Monitor frequently for symptoms of upper GI disease. Leukopenia and elevations of lactate dehydrogenase reported; perform periodic blood counts and LFTs with long-term therapy.

ADVERSE REACTIONS

Sedation, dizziness, weakness, unsteadiness.

DRUG INTERACTIONS

Increased CNS-depressant effects with other CNS depressants (eg, alcohol, barbiturates, antipsychotics, sedative/hypnotics, anxiolytics, antidepressants, narcotic analgesics, sedative antihistamines, anticonvulsants, anesthetics); may lead to potentially fatal respiratory depression. Concomitant use with clozapine may produce marked sedation, excessive salivation, hypotension, ataxia, delirium, and respiratory arrest. Increased plasma concentrations with valproate and more rapid onset or prolonged effect with probenecid; reduce dose by 50%. Decreased sedative effects with theophylline or aminophylline.

PREGNANCY AND LACTATION

Not for use in pregnancy/nursing.

MECHANISM OF ACTION

Benzodiazepine; has a tranquilizing action on the CNS with no appreciable effect on the respiratory or cardiovascular systems.

PHARMACOKINETICS

Absorption: Readily absorbed. Absolute bioavailability (90%); (2mg) C_{max}=20ng/mL; T_{max}=2 hrs. **Distribution:** Plasma protein binding (85%); found in breast milk. **Metabolism:** Glucuronidation. **Elimination:** Urine; $T_{1/2}$=12 hrs.

ASSESSMENT

Assess for acute narrow-angle glaucoma, primary depressive disorder, psychosis, personality disorders, compromised respiratory function, impaired renal/hepatic function, hepatic encephalopathy, history of alcohol/drug abuse, previous hypersensitivity to the drug, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for respiratory depression, physical/psychological dependence, withdrawal symptoms, tolerance, abuse, suicidal thinking, paradoxical reactions, symptoms of upper GI disease, and emergence/worsening of depression. Reassess usefulness of drug periodically. Monitor elderly/debilitated frequently and addiction-prone individuals carefully. Perform periodic blood counts and LFTs with long-term therapy.

PATIENT COUNSELING

Inform that psychological/physical dependence may occur; instruct to consult physician before increasing dose or abruptly d/c drug. Warn not to operate dangerous machinery or motor vehicles and that tolerance for alcohol and other CNS depressants will be diminished. Advise to consult physician if pregnancy occurs.

STORAGE

(Sol) 2-8°C (36-46°F). Protect from light. Discard opened bottle after 90 days. (Tab) 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

Back to top