Tranxene (clorazepate dipotassium) - Drug Summary

Recordati Rare Diseases, Inc.

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Tranxene (clorazepate dipotassium)

THERAPEUTIC CLASS

Benzodiazepine

DEA CLASS

CIV

ADULT DOSAGE & INDICATIONS

Anxiety Disorders

Management or Short-Term Relief:
Usual: 30mg/day in divided doses
Titrate: May adjust gradually w/in the range of 15-60mg/day

When administered as a single daily dose hs, initial dose is 15mg; may require dosage adjustment

Alcohol Withdrawal

Symptomatic Relief of Acute Withdrawal:
Day 1: 30mg initially, then 30-60mg in divided doses
Day 2: 45-90mg in divided doses
Day 3: 22.5-45mg in divided doses
Day 4: 15-30mg in divided doses
Titrate: Gradually reduce dose to 7.5-15mg/day; d/c when stable
Max: 90mg/day

Partial Seizures

Adjunctive Therapy:

Max Initial: 7.5mg tid
Titrate: Increase by no more than 7.5mg/week
Max: 90mg/day

PEDIATRIC DOSAGE & INDICATIONS

Partial Seizures

Adjunctive Therapy:

9-12 Years:
Max Initial: 7.5mg bid
Titrate: Increase by no more than 7.5mg/week
Max: 60mg/day

>12 Years:
Max Initial: 7.5mg tid
Titrate: Increase by no more than 7.5mg/week
Max: 90mg/day

DOSING CONSIDERATIONS

Elderly
Elderly/Debilitated:
Anxiety:
Initial: 7.5-15mg/day

ADMINISTRATION

Oral route

HOW SUPPLIED

Tab: 3.75mg*, 7.5mg*, 15mg* *scored

CONTRAINDICATIONS

Known hypersensitivity to the drug, acute narrow-angle glaucoma.

WARNINGS/PRECAUTIONS

Avoid w/ depressive neuroses or psychotic reactions. May impair mental/physical abilities. Withdrawal symptoms (eg, delirium, tremors, abdominal and muscle cramps, insomnia, irritability, memory impairment) may occur following abrupt discontinuation; taper gradually following extended therapy. Caution w/ known drug dependency or renal/hepatic impairment. May increase the risk of suicidal thoughts and behavior; monitor for emergence or worsening of depression, suicidal thoughts or behavior, and/or any unusual changes in mood or behavior. Suicidal tendencies may be present in patients who have depression along w/ anxiety; least amount of drug that is feasible should be available to such patients. Caution in elderly/debilitated; dose adjustments should be made slowly to preclude ataxia or excessive sedation.

ADVERSE REACTIONS

Drowsiness, dizziness, GI complaints, nervousness, blurred vision, dry mouth, headache, mental confusion.

DRUG INTERACTIONS

Additive CNS depression w/ CNS depressants, and alcohol. Barbiturates, narcotics, phenothiazines, MAOIs, and other antidepressants may potentiate the actions of the benzodiazepines. Increased sedation w/ hypnotics.

PREGNANCY AND LACTATION

Pregnancy: An increased risk of congenital malformation associated w/ the use of minor tranquilizers (eg, chlordiazepoxide, diazepam, meprobamate) during the 1st trimester of pregnancy has been suggested in several studies. Clorazepate has not been studied adequately to determine the risk of fetal abnormality; its use during pregnancy should almost always be avoided.
Lactation: Not for use in nursing.

MECHANISM OF ACTION

Benzodiazepine; antianxiety/hypnotic agent that has CNS depressant effects.

PHARMACOKINETICS

Distribution: (Nordiazepam) Found in breast milk; plasma protein binding (97-98%). **Metabolism:** Liver; rapidly decarboxylated to nordiazepam (primary metabolite); hydroxylation. **Elimination:** Urine (62-67%), feces (15-19%); (Nordiazepam) $T_{1/2}$=40-50 hrs.

ASSESSMENT

Assess for acute narrow-angle glaucoma, renal/hepatic impairment, depressive neurosis, psychotic reactions, depression, hypersensitivity to drug, pregnancy/nursing status, and for possible drug interactions. Assess psychological potential for drug dependence.

MONITORING

Monitor for signs/symptoms of depression, suicidal thoughts or behavior, unusual changes in mood or behavior, drug dependence, withdrawal symptoms, and other adverse reactions. Monitor blood counts and LFTs periodically w/ prolonged therapy.

PATIENT COUNSELING

Inform about benefits/risks and appropriate use of therapy. Counsel patients, caregivers, and family members that therapy may increase the risk of suicidal thoughts and behavior and advise of the need to be alert for the emergence or worsening of signs and symptoms of depression, any unusual changes in mood/behavior, suicidal thoughts/behavior, or thoughts about self-harm; instruct to immediately report behaviors of concern. Caution against engaging in hazardous tasks requiring mental alertness (eg, operating machinery/driving). Inform that therapy may produce psychological and physical dependence; instruct to contact physician before either increasing the dose or discontinuing therapy. Encourage patients to enroll in the North American Antiepileptic Drug Pregnancy Registry if they become pregnant.

STORAGE

20-25°C (68-77°F). Protect from moisture.

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