Campral (acamprosate calcium) - Drug Summary

Forest Laboratories, Inc.

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Campral (acamprosate calcium)

THERAPEUTIC CLASS

GABA analogue

DEA CLASS

RX

ADULT DOSAGE & INDICATIONS

Alcohol Dependence

Maint of Abstinence from Alcohol in Patients w/ Alcohol Dependence Who are Abstinent at Treatment Initiation:
Usual: Two 333mg tabs tid; a lower dose may be effective in some patients

Initiate treatment as soon as possible after the period of alcohol withdrawal, when patient has achieved abstinence, and maintain if patient relapses; use as part of a comprehensive psychosocial treatment program

DOSING CONSIDERATIONS

Renal Impairment
Moderate (CrCl 30-50mL/min):
Initial: One 333mg tab tid

ADMINISTRATION

Oral route

Take w/o regard to meals

HOW SUPPLIED

Tab, Delayed Release: 333mg

CONTRAINDICATIONS

Severe renal impairment (CrCl ≤30mL/min).

WARNINGS/PRECAUTIONS

Treatment should be initiated as soon as possible after the period of alcohol withdrawal and should be maintained if the patient relapses. Suicidal events reported. Does not eliminate or diminish withdrawal symptoms. Caution with moderate renal impairment and in elderly.

ADVERSE REACTIONS

Diarrhea, insomnia, anxiety, depression, asthenia, anorexia, pain, flatulence, nausea, dizziness, pruritus, dry mouth, paresthesia, sweating.

DRUG INTERACTIONS

Weight gain/loss may occur with concomitant antidepressants.

PREGNANCY AND LACTATION

Category C, caution in nursing.

MECHANISM OF ACTION

Gamma-aminobutyric acid (GABA) analog; has not been established. Suspected to interact with glutamate and GABA neurotransmitter systems centrally, and to remedy the imbalance between neuronal excitation and inhibition caused by chronic alcohol intake.

PHARMACOKINETICS

Absorption: Absolute bioavailability (11%); C_{max}=350ng/mL, T_{max}=3-8 hrs. **Distribution:** (IV) V_d=72-109L. **Elimination:** Kidneys (unchanged); $T_{1/2}$=20-33 hrs.

ASSESSMENT

Assess for renal impairment, drug hypersensitivity, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for development of symptoms of depression or suicidal thinking, renal dysfunction, and other adverse reactions.

PATIENT COUNSELING

Inform that a lower dose is recommended for patients with moderate renal impairment and therapy is contraindicated with severe renal impairment. Instruct family and caregivers to monitor patients for the emergence of symptoms of depression/suicidality and to report such symptoms to physician. Inform that use of drug does not eliminate or diminish withdrawal symptoms. Instruct to notify physician if become pregnant or intend to become pregnant, and breastfeeding. Advise to continue therapy ud, even in the event of relapse; remind patient to discuss any renewed drinking with physician. Advise that therapy has been shown to help maintain abstinence only when used as part of treatment program that includes counseling and support.

STORAGE

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

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