Klonopin (clonazepam) - Drug Summary

Genentech, Inc.

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Clonazepam
(clonazepam)

COMMON BRAND NAMES

Klonopin, Clonazepam

THERAPEUTIC CLASS

Benzodiazepine

DEA CLASS

CIV

ADULT DOSAGE & INDICATIONS

Seizures

Treatment of Lennox-Gastaut syndrome (petit mal variant), akinetic, and myoclonic seizures. May be useful in patients w/ absence seizures (petit mal) who have failed to respond to succinimides

Initial: Not to exceed 1.5mg/day divided into 3 doses
Titrate: May increase in increments of 0.5-1mg every 3 days until seizures are controlled or until side effects preclude any further increase
Maint: Individualize dose
Max: 20mg/day

Panic Disorder

Initial: 0.25mg bid
Titrate: May increase to target dose of 1mg/day after 3 days; for some, may increase in increments of 0.125-0.25mg bid every 3 days until panic disorder is controlled or until side effects make further increases undesired
Max: 4mg/day

PEDIATRIC DOSAGE & INDICATIONS

Seizures

Treatment of Lennox-Gastaut syndrome (petit mal variant), akinetic, and myoclonic seizures. May be useful in patients w/ absence seizures (petit mal) who have failed to respond to succinimides

≤10 Years or ≤30kg:
Initial: 0.01-0.03mg/kg/day up to 0.05mg/kg/day given in 2 or 3 divided doses
Titrate: May increase by no more than 0.25-0.5mg every 3 days until daily maintenance dose is reached, unless seizures are controlled or until side effects preclude further increase
Maint: 0.1-0.2mg/kg/day divided into 3 doses. Whenever possible, divide daily dose into 3 equal doses; give the largest dose qhs if doses are not equally divided

ADMINISTRATION

Oral route

To reduce somnolence, may give 1 dose at hs.

Tab, Disintegrating
Peel back foil on blister; do not push tab through foil.
Using dry hands, remove tab and place it in mouth.

Tab
Swallow whole w/ water.

HOW SUPPLIED

Tab, Disintegrating: 0.125mg, 0.25mg, 0.5mg, 1mg, 2mg; (Klonopin) **Tab:** 0.5mg*, 1mg, 2mg *scored

CONTRAINDICATIONS

History of sensitivity to benzodiazepines, significant liver disease, acute narrow angle glaucoma.

WARNINGS/PRECAUTIONS

May be used with treated open angle glaucoma. May impair mental/physical abilities. May increase risk of suicidal thoughts/behavior. Caution with use in pregnancy and women of childbearing potential; may increase risk of congenital malformations. Avoid use during the 1st trimester of pregnancy. May increase incidence or precipitate the onset of generalized tonic-clonic seizures in patients in whom several different types of seizure disorders coexist; addition of appropriate anticonvulsants or increase in their dosages may be required. Withdrawal symptoms reported after discontinuation. Abrupt withdrawal of therapy may precipitate status epilepticus; gradual withdrawal is essential, and simultaneous substitution of another anticonvulsant may be indicated while therapy is being gradually withdrawn. May produce an increase in salivation; caution with chronic respiratory diseases. Caution with renal impairment, addiction-prone individuals, and in elderly. (Tab, Disintegrating) Contains phenylalanine.

ADVERSE REACTIONS

CNS depression, ataxia, drowsiness, abnormal coordination, depression, somnolence, behavior problems, dizziness, URTI, memory disturbance, dysmenorrhea, fatigue, influenza, nervousness, sinusitis.

DRUG INTERACTIONS

CYP450 inducers (eg, phenytoin, carbamazepine, phenobarbital), and propantheline may decrease levels. Caution with CYP3A inhibitors (eg, oral antifungals). Alcohol, narcotics, barbiturates, nonbarbiturate hypnotics, antianxiety agents, phenothiazines, thioxanthene and butyrophenone antipsychotics, MAOIs, TCAs, other anticonvulsant drugs, and other CNS depressant drugs may potentiate CNS-depressant effects. May produce absence status with valproic acid.

PREGNANCY AND LACTATION

Pregnancy: Category D.
Lactation: Not for use in nursing.

MECHANISM OF ACTION

Benzodiazepine; has not been established. Suspected to be related to its ability to enhance activity of gamma-aminobutyric acid, the major inhibitory neurotransmitter in the CNS.

PHARMACOKINETICS

Absorption: Rapid and complete. Absolute bioavailability (90%); T_{max}=1-4 hrs. **Distribution:** Plasma protein binding (85%). **Metabolism:** Liver via CYP450 (including CYP3A), acetylation, hydroxylation, and glucuronidation. **Elimination:** Urine (<2% unchanged); $T_{1/2}$=30-40 hrs.

ASSESSMENT

Assess for drug/benzodiazepine hypersensitivity, significant liver disease, acute narrow angle glaucoma, mental depression, history of drug or alcohol addiction, renal/hepatic impairment, chronic respiratory diseases, pregnancy/nursing status, and possible drug interactions.

MONITORING

Monitor for CNS depression, emergence or worsening of depression, suicidal thoughts/behavior, unusual changes in mood or behavior, worsening of seizures, withdrawal symptoms upon discontinuation, and other adverse reactions. Periodically monitor blood counts and LFTs during long-term therapy.

PATIENT COUNSELING

Instruct to take only as prescribed. Inform that therapy may produce psychological and physical dependence; instruct to consult physician before either increasing the dose or abruptly discontinuing the drug. Caution about operating hazardous machinery, including automobiles. Counsel that drug may increase risk of suicidal thoughts and behavior; advise of the need to be alert for the emergence/worsening of symptoms of depression, any unusual changes in mood or behavior, or the emergence of suicidal thoughts, behavior, or thoughts of self-harm and immediately report to physician behaviors of concern. Advise to notify physician if becomes pregnant or intends to become pregnant during therapy; encourage enrollment in the North American Antiepileptic Drug Pregnancy Registry. Advise not to breastfeed while on therapy. Advise to inform physician if taking, or planning to take, any prescription or OTC drugs and to avoid alcohol while on therapy. (Tab, Disintegrating) Inform that drug contains phenylalanine.

STORAGE

(Tab, Disintegrating) 20-25°C (68-77°F). (Tab) 25°C (77°F); excursions permitted to 15-30°C (59-86°F).

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