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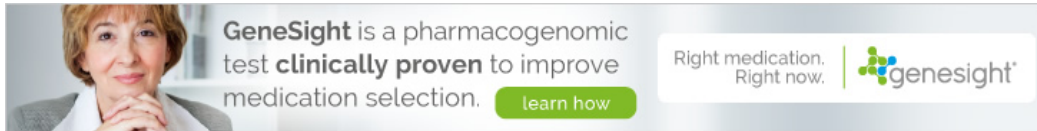
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Nembutal (pentobarbital sodium) - Drug Summary

Oak Pharmaceuticals, Inc.

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Nembutal
(pentobarbital sodium)

THERAPEUTIC CLASS

Barbiturate

DEA CLASS

CII

ADULT DOSAGE & INDICATIONS

Sedative/Hypnotic

Used as a sedative; hypnotic, for short-term treatment of insomnia; or preanesthetic

IM:

Usual: 150-200mg (max 5mL/inj) as a single inj

IV:

70kg:

Initial: 100mg

Titrate: At least 1 min is necessary to determine full effect; if necessary, may give additional small increments up to 200-500mg total dose

Max Rate: 50mg/min

Anticonvulsant

Anticonvulsant, in anesthetic doses, in the emergency control of certain acute convulsive episodes (eg, status epilepticus, cholera, eclampsia, meningitis, tetanus, toxic reactions to strychnine or local anesthetics)

In convulsive states, dose should be kept to a minimum to avoid compounding the depression that may follow convulsions; inj must be made slowly w/ due regard to the time required for the drug to penetrate the blood-brain barrier

PEDIATRIC DOSAGE & INDICATIONS

Sedative/Hypnotic

Used as a sedative; hypnotic, for short-term treatment of insomnia; or preanesthetic

IM:

Usual: 2-6mg/kg as a single inj

Max: 100mg

IV:

Proportionally reduce adult dose

Anticonvulsant

Anticonvulsant, in anesthetic doses, in the emergency control of certain acute convulsive episodes (eg, status epilepticus, cholera, eclampsia, meningitis, tetanus, toxic reactions to strychnine or local anesthetics)

In convulsive states, dose should be kept to a minimum to avoid compounding the depression that may follow convulsions; inj must be made slowly w/ due regard to the time required for the drug to penetrate the blood-brain barrier

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DOSING CONSIDERATIONS

Renal Impairment

Reduce dose

Hepatic Impairment

Hepatic Disease: Reduce dose

Elderly

Elderly/Debilited: Reduce dose

ADMINISTRATION

IM/IV routes

IM

Administer deeply into a large muscle

Do not exceed a volume of 5mL at any one site

IV

Do not mix w/ any other medication or sol

IV inj is restricted to conditions in which other routes are not feasible

Slow IV inj is essential; carefully observe patients during administration

HOW SUPPLIED

Inj: 50mg/mL [20mL, 50mL]

CONTRAINDICATIONS

History of manifest or latent porphyria.

WARNINGS/PRECAUTIONS

Used only when oral administration is impossible or impractical. May be habit-forming; tolerance, psychological and physical dependence may occur w/ continued use. Limit the amount required for the interval until the next appointment to minimize the possibility of overdosage or the development of dependence. Abrupt cessation after prolonged use in the dependent patient may result in withdrawal symptoms; withdraw gradually from any patient taking excessive dose over long periods of time. May induce paradoxical excitement or mask important symptoms in patients w/ acute or chronic pain; caution in these patients. Caution w/ mental depression, suicidal tendencies, or history of drug abuse. May cause fetal harm. May cause marked excitement, depression, and confusion in elderly or debilitated patients. Caution w/ hepatic damage; reduce initial dose. Avoid use in patients showing the premonitory signs of hepatic coma. Avoid perivascular extravasation or intra-arterial inj; extravascular inj may cause local tissue damage w/ subsequent necrosis while consequences of intra-articular inj may vary from transient pain to gangrene of the limb. D/C inj if limb pain develops. Caution in elderly. (IV) Too rapid administration may cause respiratory depression, apnea, laryngospasm, or vasodilation w/ fall in BP.

ADVERSE REACTIONS

Somnolence, agitation, confusion, hyperkinesia, ataxia, CNS depression, nightmares, psychiatric disturbance, hypoventilation, apnea, bradycardia, hypotension, syncope, N/V, constipation.

DRUG INTERACTIONS

May lower plasma levels of dicumarol, and may cause a decrease in anticoagulant activity as measured by PT. May induce hepatic microsomal enzymes resulting in increased metabolism and decreased anticoagulant response of oral anticoagulants (eg, warfarin, acenocoumarol, dicumarol, phenprocoumon). May require dose adjustment of anticoagulants or corticosteroids if barbiturates are added to or withdrawn from the dosage regimen. May enhance metabolism of exogenous corticosteroids. May decrease blood level of griseofulvin; avoid concomitant use. May shorten $T_{1/2}$ of doxycycline for as long as 2 weeks after barbiturate therapy is discontinued; monitor response to doxycycline closely if given concurrently. Monitor phenytoin and barbiturate blood levels frequently when given concurrently. Sodium valproate and valproic acid may decrease metabolism; monitor barbiturate blood levels and adjust dose as indicated. May produce additive depressant effects w/ other CNS depressants (eg, other sedatives or hypnotics, antihistamines, tranquilizers, or alcohol). MAOIs may prolong effects. Pretreatment or concurrent use may decrease effect of estradiol. Pregnancy may occur during treatment w/ antiepileptics while taking oral contraceptives; use of alternative contraceptive method is recommended.

PREGNANCY AND LACTATION

Category D, caution in nursing.

MECHANISM OF ACTION

Barbiturate; depresses the sensory cortex, decreases motor activity, alters cerebellar function, and produces drowsiness, sedation, and hypnosis.

PHARMACOKINETICS

Distribution: Distributed to all tissues and fluids; bound to plasma proteins in varying degrees; found in breast milk; crosses placenta. **Metabolism:** Hepatic microsomal enzyme system. **Elimination:** Urine (approx 25-50% unchanged), feces; $T_{1/2}$ =15-50 hrs.

ASSESSMENT

Assess for known barbiturate sensitivity, history of manifest or latent porphyria, presence of acute or chronic pain, depression, suicidal ideation, history of drug abuse, hepatic/renal impairment, pregnancy/nursing status, and possible drug interactions. Assess use in pediatrics, elderly, or debilitated patients.

MONITORING

Monitor for signs and symptoms of CNS depression, tolerance, psychological and physical dependence, withdrawal symptoms, extravasation, inj-site reactions, pain in limbs, and other adverse reactions. Monitor for induced paradoxical excitement and for masking of symptoms in patients w/ acute or chronic pain. Monitor for marked excitement, depression, and confusion in elderly and debilitated patients. Perform periodic laboratory evaluation of organ systems, including hematopoietic, renal, and hepatic systems during prolonged therapy. Monitor vital signs after IM inj of a hypnotic dose. Monitor BP, respiration, cardiac function, vital signs, and rate of inj during IV administration.

PATIENT COUNSELING

Inform of the possibility of physiological and/or physical dependence. Instruct to avoid increasing the dose w/o consulting a physician. Inform that the drug may impair mental/physical abilities required for the performance of hazardous tasks (eg, operating machinery, driving). Instruct to avoid alcohol intake while on therapy. Inform that use of other CNS depressants may result in additional CNS depressant effects.

STORAGE

20-25°C (68-77°F); brief excursions permitted between 15-30°C (59-86°F). Avoid excessive heat. Protect from freezing.

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