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Phenobarbital Tablets (15 mg, 30 mg, 60 mg, 100 mg) (phenobarbital) - Drug Summary

West-ward Pharmaceutical Corp.

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Related Drug Information

Phenobarbital
(phenobarbital)

THERAPEUTIC CLASS

Barbiturate

DEA CLASS

CIV

ADULT DOSAGE & INDICATIONS

Sedation

Sedative:

Tab (15mg, 30mg, 60mg, 100mg):

30-120mg in 2-3 divided doses

Tab (16.2mg, 32.4mg, 64.8mg, 97.2mg):

30-120mg in 2-3 divided doses; individualize frequency by patient response

Doses >400mg/24 hrs not recommended

Elixir:

30-120mg in 2-3 divided doses; individualize dose based on patient response

Doses >400mg/24 hrs not recommended

Hypnotic:

Tab (15mg, 30mg, 60mg, 100mg):

100-320mg

Tab (16.2mg, 32.4mg, 64.8mg, 97.2mg):

100-200mg

Elixir:

100-200mg

Seizures

Generalized/Partial Seizures:

Tab (16.2mg, 32.4mg, 64.8mg, 97.2mg):

60-200mg/day

Elixir:

60-200mg/day

Anticonvulsant:

Tab (15mg, 30mg, 60mg, 100mg):

50-100mg bid or tid

PEDIATRIC DOSAGE & INDICATIONS

Sedation

Tab (15mg, 30mg, 60mg, 100mg):

6mg/kg/day in 3 divided doses

Seizures

Generalized/Partial Seizures:

Tab (16.2mg, 32.4mg, 64.8mg, 97.2mg):

3-6mg/kg/day

Elixir:

3-6mg/kg/day

Also used in the treatment/prophylaxis of febrile seizures

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Anticonvulsant:
Tab (15mg, 30mg, 60mg, 100mg):
15-50mg bid or tid

DOSING CONSIDERATIONS

Renal Impairment

Reduce dose

Hepatic Impairment

Reduce dose

Elderly

Elderly/Debilitated: Reduce dose

ADMINISTRATION

Oral route

HOW SUPPLIED

Elixir: 20mg/5mL [473mL]; Tab: 15mg, 16.2mg*, 30mg*, 32.4mg*, 60mg, 64.8mg*, 97.2mg*, 100mg* *scored

CONTRAINDICATIONS

Marked impairment of liver function or respiratory disease in which dyspnea or obstruction is evident. (Elixir/16.2mg, 32.4mg, 64.8mg, 97.2mg Tab) History of manifest/latent porphyria. (15mg, 30mg, 60mg, 100mg Tab) Personal or familial history of acute intermittent porphyria, known previous addiction to sedative/hypnotic group.

WARNINGS/PRECAUTIONS

Caution w/ borderline hypoadrenal function and history of drug abuse or dependence. Caution in patients who are mentally depressed or w/ suicidal tendencies. Caution when prescribing large amounts to patients w/ a history of emotional disturbances. Elderly or debilitated patients may react w/ marked excitement, depression, or confusion. (15mg, 30mg, 60mg, 100mg Tab) May increase reaction to painful stimuli in small doses; cannot be relied upon to relieve pain or even produce sedation or sleep in the presence of severe pain if taken alone. Caution w/ decreased liver function. (Elixir/16.2mg, 32.4mg, 64.8mg, 97.2mg Tab) Caution w/ acute or chronic pain; may induce paradoxical excitement or mask important symptoms. Some persons, especially children, may repeatedly produce excitement rather than depression. Avoid in patients showing premonitory signs of hepatic coma. May cause fetal damage. Use during labor may result in respiratory depression in the newborn. Cognitive deficits reported in children taking drug for complicated febrile seizures. May be habit-forming; limit prescription and dispensing to amount required for the interval until the next appointment. Withdraw gradually in patients taking excessive doses over long periods of time.

ADVERSE REACTIONS

Respiratory/CNS depression, apnea, circulatory collapse, hypersensitivity reactions, N/V, headache, somnolence.

DRUG INTERACTIONS

May produce additive depressant effects w/ other CNS depressants (eg, other sedatives/hypnotics, antihistamines, tranquilizers, alcohol). May diminish systemic effects of exogenous corticosteroids (eg, hydrocortisone). Decreased anticoagulant response of oral anticoagulants (eg, warfarin, acenocoumarol, dicumarol, phenprocoumon); determine PT frequently. Dose adjustments of anticoagulants may be required if barbiturates are added to or withdrawn from the dosage regimen. (Elixir/16.2mg, 32.4mg, 64.8mg, 97.2mg Tab) Dose adjustments of corticosteroids may be required if barbiturates are added to or withdrawn from the dosage regimen. May decrease griseofulvin levels; 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. Increased levels w/ sodium valproate and valproic acid; closely monitor barbiturate blood levels and adjust dose as indicated. MAOIs may prolong effects. May decrease effect of estradiol w/ pretreatment or w/ concurrent use. Pregnancy reported w/ oral contraceptives; may suggest use of alternative contraceptive method.

PREGNANCY AND LACTATION

Category B (15mg, 30mg, 60mg, 100mg Tab) and D (Elixir/16.2mg, 32.4mg, 64.8mg, 97.2mg Tab), caution in nursing.

MECHANISM OF ACTION

Barbiturate; CNS depressant. Depresses sensory cortex, decreases motor activity, alters cerebellar function, and produces drowsiness, sedation, and hypnosis.

PHARMACOKINETICS

Distribution: Crosses the placenta; found in breast milk. **Metabolism:** Hepatic. **Elimination:** Urine (25-50% unchanged), feces; $T_{1/2}$ =53-118 hrs (adults), 60-180 hrs (children and newborns <48 hrs old).

ASSESSMENT

Assess for known barbiturate hypersensitivity, history of porphyria, respiratory disease w/ evident dyspnea or obstruction, hypoadrenal function, suicidal tendencies, history of drug abuse or dependence, mental depression, hepatic impairment, debilitation, pain, pregnancy/nursing status, and possible drug interactions. (Elixir/16.2mg, 32.4mg, 64.8mg, 97.2mg Tab) Assess for renal impairment.

MONITORING

Monitor for marked excitement, depression, and confusion in elderly and debilitated patients. Monitor for tolerance, psychological and physical dependence, and withdrawal symptoms. Monitor PT frequently if used w/ coumarin anticoagulants. (Elixir/16.2mg, 32.4mg, 64.8mg, 97.2mg Tab) Monitor for paradoxical excitement and for masking of symptoms in patients w/ acute/chronic pain. Monitor for cognitive deficits in children w/ complicated febrile seizures. Perform periodic lab evaluation of hematopoietic, renal, and hepatic systems during prolonged therapy.

PATIENT COUNSELING

Inform that medication may impair mental/physical abilities required for the performance of potentially hazardous tasks (eg, driving/operating machinery); advise to use caution. (Elixir/16.2mg, 32.4mg, 64.8mg, 97.2mg Tab) Inform of the risk of psychological and/or physical dependence; instruct not to increase dose w/o consulting physician. Instruct to avoid alcohol while on therapy; inform that use of other CNS depressants (eg, alcohol, narcotics, tranquilizers, antihistamines) may result in additional CNS depressant effects.

STORAGE

20-25°C (68-77°F). (15mg, 30mg, 60mg, 100mg Tab) Protect from light and moisture.

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