










Phenobarbital Phenobarbital Phenobarbital Phenobarbital Phenobarbital

PHENOBARBITAL

Scored tablets

Category

Sedative-hypnotic, Anticonvulsant and Antihyperbilirubinemic.

Indications

Anesthesia adjunct, treatment of Epilepsy, tonic-clonic seizure pattern and simple partial seizure pattern and Convulsions, prophylaxis and treatment of seizures, treatment of status epilepticus, tetanus treatment adjunct prophylaxis and treatment of febrile seizures, prevention and treatment of hyperbilirubinemia in neonates, short-term treatment of insomnia.

Pharmacology/Pharmacokinetics

Phenobarbital acts as nonselective depressants of the central nervous system and depressing monosynaptic and polysynaptic transmission in the CNS. Phenobarbital lowers serum bilirubin concentrations probably by induction of glucuronyl transferase, the enzyme which conjugates bilirubin. Phenobarbital absorbed orally and rapidly distributed to all tissues.

Pregnancy/ Breast feeding

FDA Pregnancy Category is D. Phenobarbital has been shown to cause an increased incidence of fetal abnormalities. Risk-benefit must be carefully considered when the medication is required in life-threatening situations or in serious diseases for which other medications cannot be used or are ineffective. Phenobarbital is distributed into breast milk; use by nursing mothers may cause CNS depression in the infant.

Drug interactions and/or related problems

Because of increased metabolism resulting from induction of hepatic microsomal enzymes on Phenobarbital administration, the hepatic metabolism of most medicaments can be affected by Phenobarbital. This subject should be observed by physician.

Medical considerations/Contraindications

Except under special circumstances, this medication should not be used when the following medical problem exists

Porphyria

Risk-benefit should be considered when the following medical problems exist

Anemia, Asthma, Diabetes mellitus, Drug abuse or dependence, Hepatic coma, Hepatic function impairment, Hyperkinesia, Hyperthyroidism, Hypoadrenalism, Mental depression, Suicidal tendencies, Pain, Renal function impairment, Sensitivity to barbiturate prescribed.

Side/Adverse Effects

Exfoliative dermatitis and Stevens-Johnson syndrome, possibly fatal, may occur rarely as hypersensitivity reactions to barbiturates. If dermatologic reactions occur, the barbiturate should be discontinued. Severe respiratory depression, prolonged barbiturate therapy may result in osteopenia or rickets. Barbiturate dependence may occur, especially following prolonged use of high doses.

Those indicating need for medical attention

Incidence less frequent:

Sensitivity to barbiturates; mental depressions; paradoxical reaction

Incidence rare:

Agranulocytosis; allergic reaction; exfoliative dermatitis; hallucinations; hypotension or megaloblastic anemia; thrombophlebitis.

Those indicating need for medical attention only if they continue or are bothersome

Incidence more frequent:

Clumsiness or unsteadiness; dizziness or lightheadedness; drowsiness; "hangover" effect.

Incidence less frequent:

Anxiety or nervousness; constipation; feeling faint; headache; irritability; nausea or vomiting; nightmares or trouble in sleeping.

Phenobarbital withdrawal need for medical attention if they occur after medication is discontinued.

Overdose

For the management of overdose or unintentional ingestion, contact a Poison Control Center immediately.

Dosing

Usual adult dose

Anticonvulsant: 60 to 250 mg per day, as a single dose or in divided doses.

Sedative-hypnotic: 100 to 320 mg (base) at bedtime.

Sedative (Daytime): 30 to 120 mg in two or three divided doses a day.

Antihyperbilirubinemic: 30 to 60 mg three times a day.

Usual pediatric dose

Anticonvulsant: 1 to 6 mg per kg of body weight per day, as a single dose or in divided doses.

Sedative-hypnotic: Dosage must be individualized by physician.

Sedative (Daytime): 2 mg per kg of body weight three times a day.

Preoperative: 1 to 3 mg per kg of body weight.

Antihyperbilirubinemic:

Neonates: 5 to 10 mg per kg of body weight per day for the first few days after birth.

Children up to 12 years of age: 1 to 4 mg per kg of body weight three times a day.

How supplied

15, 60 and 100 mg tablets; 10 blisters of 10's in a folding box with the leaflet.

Storage

Store below 30 °C, protect from direct sunlight and moisture.



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