

Epinal[®]

Phenobarbital USP

COMPOSITION

Epinal[®] 30 tablet: Each tablet contains Phenobarbital USP 30 mg.

Epinal[®] 60 tablet: Each tablet contains Phenobarbital USP 60 mg.

Epinal[®] Elixir : Each 5 ml contains Phenobarbital USP 20 mg.

Epinal[®] Injection : Each 1 ml ampoule contains Phenobarbital USP 200 mg.

PHARMACOLOGY

Phenobarbital is a long-acting barbiturate with sedative, hypnotic and anticonvulsant effects. It depresses sensory cortex, decreases motor activity, alters cerebella function and produces drowsiness, sedation and hypnosis. Its anticonvulsant property is exhibited at high doses.

INDICATION

Phenobarbital is used as:-

- Sedative and hence it relieves anxiety, tension and fear
- Hypnotic and hence it is used for short term insomnia
- Pre-anaesthetics
- Anti-epileptic in epilepsy with Partial seizure or Generalized Tonic-clonic seizure, status epilepticus
- Certain acute convulsive episodes

DOSAGE & ADMINISTRATION

Adults:

Hypnosis: 100 to 320 mg

Sedation: 30 to 120 mg/day in 2 to 3 divided doses

Epilepsy: 60 to 250 mg/day

Convulsion: 50 to 100 mg/day in 2 to 3 divided doses

Status epilepticus: IV 10-20 mg/Kg, repeat if needed

Children:

Preoperative: 1-3 mg/Kg body weight

Convulsion: 4-6 mg/Kg/day

Status epilepticus: IV 15-20 mg/Kg over 10-15 minutes

CONTRAINDICATION

Phenobarbital is contraindicated in patients with acute intermittent porphyria and who have a natural or idiosyncrasy to barbiturates.

PRECAUTION

Phenobarbital is potentially habit forming if taken over an extended period of time. When being prescribed to overcome insomnia, the drug should not be used for a period longer than two weeks. Caution should be taken in patients who are mentally depressed, have hepatic damage, suicidal tendencies or a history of drug abuse.

PREGNANCY AND LACTATION

Pregnancy Category D

Phenobarbital can cause potential fetal damage. Their use in pregnancy alone, or in combination with other anticonvulsants, can cause coagulation defects in the newborn infant which may be preventable by the prophylactic administration of Vitamin K to the mother prior to delivery. Phenobarbital is excreted through human milk; so caution should be taken during lactation period.

SIDE EFFECT

Drowsiness is the most common side effect. Less common side effects are CNS depression, nervousness, agitation, psychiatric disturbance, lethargy, mental depression, ataxia, nightmares, bradycardia, apnea, nausea, vomiting, constipation, restlessness and confusion in the elderly and hyperkinesia in children.

DRUG INTERACTION

Phenobarbital can interact with a number of prescription and nonprescription medications including acetaminophen, anticoagulants such as warfarin, chloramphenicol, monoamine oxidase inhibitors (MAOIs), antidepressants, asthma medicine, cold medicine, anti-allergy medicine, sedatives, steroids, tranquilizers, and vitamins. Interactions with these medications can increase the drowsiness caused by phenobarbital.

OVERDOSE

Phenobarbital should not be used more than the dosage guide line. 1 gm Phenobarbital oral dose may cause serious poisoning and 2 gm may cause even death. Over dosage produces severe, persistent depression. Treatment includes artificial respiration, maintenance of fluid balance and antibiotics to prevent pneumonia. Alkalinisation of the urine and forced diuresis or haemodialysis have been used in cases of severe poisoning.

STORAGE

Protect from light, store in cool and dry place. Keep out of reach of children.

HOW SUPPLIED

Epinal[®] 30: Each box contains 100 tablets in blister pack.

Epinal[®] 60: Each box contains 100 tablets in blister pack.

Epinal[®] Elixir: Each bottle contains 100 ml elixir.

Epinal[®] Injection : Each box contains 5 ampoules in blister pack.

Manufactured by :



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