

PHENOBARBITAL SODIUM

Injection USP

(200 mg/ml)

COMPOSITION:

Each ml contains:

Phenobarbital Sodium USP	200 mg
Alcohol USP	10% v/v
Propylene Glycol USP (as solvent)	q.s.

CATEGORY:

Barbiturate.

GENERAL INFORMATION:

Phenobarbital & Amylobarbitone belong to the group Barbiturates of CNS depressants. They are hypnotic drugs.

MOA:

Barbiturates are CNS depressants. They also augment inhibitory effects of GABA. Effects range from sedation and in high doses cause anaesthesia.

INDICATIONS:

Intractable insomnia. eclampsia, spastic excitatory states. Generalised tonic clonic seizures, febrile convulsion, temporal lobe epilepsy, cortical focal seizures, status epilepticus.

DOSAGE AND ADMINISTRATION:

Adults: 30-210mg daily in divided doses.

Children: Phenobarbitone:

- 1) For sedation: PO, I.M.: 2-3 mg/kg/24hour divided every 8-12 hour.
- 2) For sleep: PO, I.M.: 2-3 mg/kg/dose, repeat sos after 12-24 hour.
- 3) Long term anticonvulsant Rx: Start with 1.5mg/kg/24 hours, divided every 12 hours, increase according to tolerance and therapeutic effect to 4-6mg/kg/24 hour divided every 12 hours or as a single daily dose, preferably at bed time.
- 4) In status epilepticus, I.V.: 10-20mg/kg loading dose by slow I.V. injection followed after interval of 5 minutes by 5-10mg/kg/dose to be repeated at 20 minute intervals until seizures are controlled or a total dose of 40mg/kg is reached.

CONTRAINDICATIONS:

Barbiturates are contraindicated in acute intermittent porphyria, uncontrolled pain and debilitated individuals and in cases of alcohol and drug abuse. Hyperkinetic children.

ADVERSE EFFECTS:

Main side effect is sedation (which disappears after a few weeks due to development of tolerance). In young and elderly it causes confusion and paradoxical excitement or agitation. Irritability and hyperactivity in children may be seen. Megaloblastic anaemia, osteomalacia and skin rashes may occur. Rarely hepatitis and agranulocytosis may occur. The toxicity is manifested by hypotension, ataxia, dizziness, respiratory depression, coma & death.

SPECIAL PRECAUTIONS:

Chronic use of barbiturates may result in intolerance and drug dependence. Barbiturates cause decreased efficacy of other drugs because of hepatic microsomal enzyme induction in liver and accelerated metabolism of oral anticoagulants, oral contraceptives and phenytoin. Respiratory insufficiency.

INTERACTIONS:

Alcohol & other CNS Depressants (other sedatives, hypnotics, anesthetics, antihistamines, tranquilizers, phenothiazines): Additive CNS depression.

Valproic acid: Increases efficacy of barbiturates. Half life of valproic acid may be decreased.

Chloramphenicol: Efficacy of barbiturates increased. Barbiturates may decrease efficacy of chloramphenicol.

MAOIs: Effects of barbiturates prolonged.

Efficacy of the following drugs decreased by barbiturates: Oral anticoagulants, digitoxin, TCAs, corticosteroids, doxycycline, oral contraceptives and estrogens, acetaminophen, beta-blockers, quinidine, rifampicin, theophylline and metronidazole.

Phenytoin: Effect on phenytoin metabolism is unpredictable.

Frusamide: May produce or aggravate orthostatic hypotension.

Griseofulvin: Interferes with absorption of oral griseofulvin leading to decreased blood levels.

STORAGE:

Store below 30°C. Protect from light.

Keep out of the reach of children.

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PRESENTATION:

10 ampoules of 1ml are in a plastic tray and each tray packed in a printed box.

Manufactured in India:

