



26600

Ref. No.: B2126600/23.02

Phenobarbital (Tablets)

Phenobarbital
Anticonvulsant

PHENOBARBITAL TABLETS 30MG

PHENOBARBITAL TABLETS 60MG

PRESENTATION:

Phenobarbital Tablets 30mg: A white, circular, flat bevelled-edge tablet embossed 'P' on one side and '30' on the other side. Each tablet contains: Phenobarbital 30mg, Lactose and other excipients.

Phenobarbital Tablets 60mg: White to off white, round, standard convex shaped tablet embossed 'COSMOS' on one side and 'breakline' on the other side. Each tablet contains: Phenobarbital 60mg, Lactose and other excipients.

CLINICAL PHARMACOLOGY:

Phenobarbital is a barbiturate that may be used as an antiepileptic to control partial and generalised tonic-clonic seizures. Phenobarbital stimulates the enzymes in hepatic microsomes responsible for the metabolism of some drugs and normal body constituents including bilirubin, and it has been used to reduce hyperbilirubinemia in neonatal jaundice.

Pharmacokinetics:

Like other barbiturates Phenobarbital is readily absorbed from the gastro-intestinal tract, although it is relatively lipid-insoluble; peak concentrations are reached in about 2 hours after oral administration and within 4 hours of intramuscular administration. Phenobarbital is about 45% to 60% bound to plasma proteins and is only partly metabolised in the liver. About 25% of a dose is excreted in the urine unchanged at normal urinary pH. The plasma half-life is about 75 to 120 hours in adults but is greatly prolonged in neonates, and shorter (about 21 to 75 hours) in children. There is considerable interindividual variation in Phenobarbital kinetics. Monitoring of plasma concentrations has been performed as an aid in assessing control and the therapeutic range of plasma-phenobarbital is usually quoted as 15 to 40 micrograms/mL (65 to 170 micromoles/litre). Phenobarbital crosses the placental barrier and is distributed into breast milk.

USES:

Phenobarbital is a barbiturate with anticonvulsant properties. It may be used as an antiepileptic to control generalised tonic-clonic (grand mal) and partial (focal) seizures.

DOSAGE AND ADMINISTRATION:

The usual dose by mouth is 60 to 180mg daily, taken at night, and a suggested dose for children is up to 8mg per kg body-weight daily. The dose should be adjusted to the needs of the individual patient to achieve adequate control of seizures.

CONTRA-INDICATIONS AND WARNINGS:

Precautions:

Phenobarbital and other barbiturates should be used with care in children and in elderly or debilitated patients, in those in acute pain, and in those with depressive disorders. Phenobarbital should be used with caution in patients with impaired hepatic, renal or respiratory function; its use is contra-indicated in those with severe respiratory depression.

Adverse effects:

The most frequent adverse effect associated with Phenobarbital is sedation, but this often becomes less marked with continued use. Phenobarbital may produce subtle mood changes and impairment of cognition and memory.

Phenobarbital (Tablets)

Prolonged use can occasionally result in folate deficiency; rarely, megaloblastic anaemia has been reported. At high doses nystagmus and ataxia may occur and the typical barbiturate-induced respiratory depression may become severe.

Treatment of Overdosage:

Overdosage produces severe, persistent respiratory depression. Overdosage can prove fatal; toxic effects include coma, severe respiratory and cardiovascular depression, with hypotension and shock leading to renal failure. Hypothermia may occur, with associated pyrexia during recovery. Skin blisters (bullae) reportedly occur in about 6% of patients with barbiturate overdose. Treatment includes general measures for the support of the respiratory and cardiovascular systems. Following an overdosage of a barbiturate, gastric lavage may be considered if undertaken within 1 to 2 hours or if the patient is unconscious. Repeated doses of activated charcoal should be given by mouth with the aim not only of preventing absorption but also of aiding elimination. Charcoal haemoperfusion may be considered for patients with severe refractory poisoning; other methods aimed at the active removal of a barbiturate with a long elimination half-life such as Phenobarbital include forced diuresis, haemodialysis, and peritoneal dialysis but the hazards of such procedures are generally considered to outweigh any purported benefits.

Interactions:

Valproate and phenytoin have been reported to cause rises in Phenobarbital (and primidone) concentrations in plasma. The effects of Phenobarbital and other barbiturates are enhanced by other CNS depressants including alcohol. Phenobarbital and other barbiturates may reduce the activity of many drugs by increasing the rate of metabolism through induction of drug-metabolising enzymes in liver microsomes.

Pregnancy and Lactation:

Pregnancy: Phenobarbital should not be used during pregnancy unless the potential benefit is judged to outweigh the risks following consideration of other suitable treatment options.

Lactation: Phenobarbital is excreted into breast milk and there is a small risk of neonatal sedation. Breast-feeding is therefore not advisable.

PHARMACEUTICAL PRECAUTIONS:

Store in a dry place below 30°C. Protect from light. Keep all medicines out of the reach of children.

LEGAL CATEGORY:

Prescription Only Medicine (POM)



Cosmos Limited,
Rangwe Rd; Off Lungu Lungu Rd,
Nairobi, Kenya