

PHENYTOIN TABLETS (Phenytoin Sodium)

COMPOSITION:

Phenytoin Tablets 50mg: Each tablet contains: Phenytoin Sodium BP 50mg.
Phenytoin Tablets 100mg: Each tablet contains: Phenytoin Sodium BP 100mg.

PHARMACOLOGY:

Phenytoin tablets contain Phenytoin Sodium which is an antiepileptic drug. The primary site of action of Phenytoin Sodium appears to be the motor cortex where spread of seizure activity is inhibited. Phenytoin Sodium tends to stabilize the threshold against hyperexcitability caused by excessive stimulation by promoting sodium efflux from neurons, thus reducing post-tetanic potentiation at synapses. Loss of post-tetanic potentiation prevents cortical seizure foci from detonating adjacent cortical areas. Phenytoin reduces the maximal activity of brain stem centres responsible for the tonic phase of tonic-clonic (grand mal) seizures.

PHARMACOKINETICS:

Phenytoin is slowly but almost completely absorbed from the gastrointestinal tract and is extensively metabolised in the liver to inactive metabolites. It is widely distributed throughout the body and is extensively bound (about 90%) to plasma proteins. Phenytoin undergoes enterohepatic recycling and is excreted in the urine, mainly as its hydroxylated metabolite, in either free or conjugated form.

INDICATIONS:

Phenytoin tablets are indicated for the control of generalized tonic-clonic (grand mal) and complex partial (focal) seizures and prevention and treatment of seizure occurring during or after neurosurgery of following severe traumatic injury to the head. It is believed to stabilize rather than alleviate the seizure threshold and to limit the spread of seizure activity.

DOSEAGE AND ADMINISTRATION:

Phenytoin tablets are administered orally with at least half a tumblerful of water either during or after meals in order to lessen gastric irritation. The dose of Phenytoin tablets should be adjusted to the needs of individual patient to achieve adequate control of seizures, preferably with monitoring of plasma concentrations.

Dosage: Adults

The recommended initial dose of Phenytoin tablets in adults is 100mg three times daily progressively increased with care to 600mg daily if necessary; the suggested interval between increments can range from one week to one month. Maintenance dose is 300 to 400mg daily.

Dosage: Children

Initial dose: 5mg per kg body weight daily in 2 to 3 divided doses.
Maintenance dose: 4mg to 8mg per kg body weight daily in divided doses. Young children may require a higher dose per kg body weight than adults due to more rapid metabolism.

Phenytoin tablets may be administered with other antiepileptic agents but single drug therapy is generally preferred unless the patient is suffering from two different forms of epilepsy which require control by different drugs.

SIDE EFFECTS

Commonly encountered side effects:

1. Anorexia, headache, dizziness, transient nervousness, insomnia and gastrointestinal disturbances such as nausea, vomiting and constipation.
2. Tenderness and hyperplasia of gums in young patients.
3. Acne, hirsutism and coarsening of facial features in adolescents and women.
4. Mild hypersensitivity reactions commonly with skin rashes, often morbilliform and which may be accompanied with fever.

Occasionally encountered side effects:

1. Symptoms of rare severe hypersensitivity reactions such as lupus erythematosus, erythema multiforme, Stevens-Johnson syndrome or toxic epidermal necrolysis.
2. Other conditions that may represent hypersensitivity reactions are: eosinophilia, lymphadenopathy, blood disorders such as a plastic anaemia, leucopenia, thrombocytopenia and agranulocytosis.

Side effects that may be encountered with prolonged treatment:

1. Subtle effects on mental function and cognition may be produced especially in children.
2. Rickets and osteomalacia may occur in those inadequately exposed to sunlight.
3. Mild peripheral neuropathies
4. Megaloblastic anaemia.

TOXIC MANIFESTATIONS

1. These manifest often as cerebellar, vestibular and ocular effects; notable are nystagmus, diplopia and ataxia; mental confusion (sometimes severe), dyskinesia, and exacerbations of seizure frequency may occur.
2. Toxic phenytoin concentrations often lead to hyperglycaemia.
3. Overdosage leads to hypotension, coma and respiratory depression.

CAUTIONS AND PRECAUTIONS

1. Phenytoin should be used with caution in diabetics and in liver malfunction.
2. Change of Phenytoin administration with other antiepileptic drugs during therapy should be gradual.
3. Withdraw treatment if leucopenia develops.
4. Patients/minders should be taught to recognise toxicity signs and advised to seek medical help if hypersensitivity reactions develop.
5. Drugs that inhibit phenytoin metabolism have the potential of raising phenytoin concentration to toxic levels.

CONTRA-INDICATIONS

1. Phenytoin is contraindicated in patients hypersensitive to phenytoin or other hydantoin.
2. Use of phenytoin in pregnancy may result in hypoprothrombinaemia and at times congenital malformations in the newborn.

TREATMENT OF TOXICITY

1. Treatment of poisoning and overdosage is supportive.
2. In severe cases gastric lavage should be carried out following phenytoin ingestion.

DRUG INTERACTIONS

- Phenytoin induces the metabolism of a number of drugs which include antibacterials, anticoagulants, corticosteroids, quinidine and oral contraceptives.

LEGAL CATEGORY: Prescription Only Medicines (POM)

THERAPEUTIC CATEGORY: ATC: NO3 (Antiepileptic)

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

SHELF LIFE: As per the product label.

PRESENTATION: Available in blister packs of 10x10's and bulk packs of 1000's

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LICENCE HOLDER: LABORATORY & ALLIED LTD



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