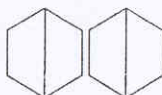


Package Insert

VIBEE TABLETS



COMPOSITION :

Each tablet contains :-

Vitamin B ₁ (Thiamine Mononitrate)	100.00 mg
Vitamin B ₆ (Pyridoxine Hydrochloride)	200.00 mg
Vitamin B ₁₂ (Cyanocobalamin)	200.00 mcg

DOSAGE FORM AVAILABLE :

ORAL : TABLET

PRODUCT DESCRIPTION :

Round, biconvex, pink film coated tablet, impressed BIOLAB's logo on one side and bisected on the obverse.

ACTIONS :

VIBEE contains essential vitamin B complex, including vitamin B₁₂. Vitamin B₁ (Thiamine mononitrate) is required for carbohydrate metabolism.

Vitamin B₆ (Pyridoxine Hydrochloride) is required for protein, fat and carbohydrate metabolism.

Vitamin B₁₂ (Cyanocobalamin) is associated with fat and carbohydrate metabolism and protein synthesis.

Thiamine combines with adenosine triphosphate (ATP) to form thiamine pyrophosphate, which acts as a coenzyme in carbohydrate metabolism.

Pyridoxine is converted to the active form, Pyridoxal phosphate, by the enzyme pyridoxal kinase. The active form acts as a coenzyme in the metabolism of protein, carbohydrate and fat.

Vitamin B₁₂ (Cyanocobalamin) can be converted to coenzyme B₁₂ in tissues and as such involves the synthesis of protein.

Moreover it is associated with fat and carbohydrate metabolism.

VIBEE contains vitamin B₁, vitamin B₆ and vitamin B₁₂, which are essential neurotropic vitamins.

INDICATIONS :

Mononeuropathies and polyneuropathies eg. diabetic, alcoholic and toxic neuropathies. Neuritis and neuralgia especially cervical syndrome, shoulder-arm syndrome, lumbago sciatica.

Deficiency or raised requirements of vitamins B₁, B₆ and B₁₂.

DOSAGE AND ADMINISTRATIONS :

Adults :

Tablet : 1-2 tablets 3 times daily to treat moderate cases, or to provide interval and follow-up therapy for a course of injections.

No sign of hypervitaminosis were noted. The tablets are swallowed, unchewed with a little liquid with or after meals.

For oral medication in injection intervals, for continuation of current injection therapy and for prevention of recidivations, it is recommended to continue with 1-2 tablets of VIBEE 3 times daily.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE AND ANTIDOTE(S) :

Parenteral doses of Thiamine 100 to 500 mg, single or repeated, have been administered without toxic effects.

Pyridoxine HCl : in animals, doses of 3 to 4 gm/kg produces convulsions and death. In man, a dose of 25 mg/kg is well tolerated.

CONTRAINDICATIONS :

VIBEE is contraindicated in patients who are hypersensitivity to Thiamine or/and Pyridoxine or/and Cyanocobalamin.

PRECAUTIONS AND WARNINGS :

A sensitivity history should be obtained from the patients prior to administration of the drug.

SIDE EFFECTS/ADVERSE REACTIONS :

Thiamine is usually nontoxic even following administration of large doses; however, feelings of warmth, tingling, pruritus, pain, urticaria, weakness, sweating, nausea, restlessness, tightness of the throat, angioedema, respiratory distress, cyanosis, pulmonary edema, GI bleeding, transient vasodilation and hypotension, vascular collapse and death have occurred occasionally, mainly following IV administration of the drug. In animals, very large parenteral doses of Thiamine have produced neuromuscular and ganglionic blockade.

Pyridoxine is usually nontoxic; however, chronic administration of large dosages of Pyridoxine has been associated adverse effects. Nausea, headache, paresthesia, somnolence, and increased serum AST (SGOT) and decreased serum folic acid concentrations have been reported.

Cyanocobalamin is usually nontoxic even in large doses, however, mild transient diarrhea, peripheral vascular thrombosis, itching, transitory exanthema, urticaria, feeling of swelling of the entire body, anaphylaxis, and death have been reported. Although allergic reactions to cyanocobalamin have generally been attributed to impurities in the preparation, a few patients have reacted positively to skin testing with purified cyanocobalamin of hydroxocobalamin.

DRUG INTERACTIONS :

Thiamine reportedly may enhance the effects of neuromuscular blocking agents.

Pyridoxine Hydrochloride reverses the therapeutic effects of levodopa by stimulating the decarboxylation of dopa to dopamine. Concomitantly administration of decarboxylase inhibitor, carbidopa, with levodopa can prevent the reversal by pyridoxine of levodopa's effects.

Pyridoxine Hydrochloride should not be administered in dosage more than 5 mg daily to patients receiving levodopa alone.

Absorption of Cyanocobalamin from GI tract may be decreased by aminoglycosides antibiotics, colchicine, anticonvulsants (e.g. phenytoin, phenobarbital, primidone), cobalt irradiation of small bowel and be excessive alcohol intake lasting longer than 2 weeks. Chloramphenicol reportedly may antagonize the hematopoietic response to vitamin B₁₂ in vitamin B₁₂ deficiency patients.

STORAGE :

Store at temperature not exceeding 30°C.

Protect from light and moisture.

The shelf-life period is 3 years.

SUPPLY :

TABLETS : Sachet in plastic bottle of 2x250's



Manufactured by
BIOLAB CO., LTD.
625 Bangpoo Industrial Estate,
Samutprakarn, Thailand