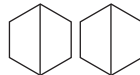


VIBEE TABLETS



COMPOSITION :

Each tablet contains-
 Vitamin B₁ (Thiamine Mononitrate) 100.00 mg
 Vitamin B₆ (Pyridoxine Hydrochloride) 200.00 mg
 Vitamin B₁₂ (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.

PHARMACODYNAMICS :

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 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.

PHARMACOKINETICS :

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

Relevant Pharmacokinetic data:

Vitamin B₁ (Thiamine Mononitrate)

- **Absorption:** It is readily absorbed following oral administration. The oral absorption is limited to about 4 - 8 mg.

GI absorption of thiamine is decreased in alcoholics and in patients with cirrhosis or malabsorption.

- **Distribution:** It is widely distributed into body tissues. Body stores of thiamine have been estimated to about 30 mg with about a 1 mg daily turnover.

- **Elimination:** Thiamine is metabolized in the liver. Little or no unchanged thiamine is excreted in urine following administration of physiologic doses.

Vitamin B₆ (Pyridoxine Hydrochloride)

- **Absorption:** It is readily absorbed following oral administration. Normal serum concentrations of pyridoxine are 30 - 80 mg/ml.

- **Distribution:** It is stored mainly in the liver with lesser amount in muscle and brain. The total body store amount of vitamin B₆ is estimated to be 16 - 27 mg. It crosses the placenta.

- **Elimination:** In the liver, pyridoxal is oxidized to 4-pyridoxic acid which is excreted in urine.

Vitamin B₁₂ (Cyanocobalamin)

- **Absorption:** Cyanocobalamin is irregularly absorbed from distal small intestine. Intrinsic factor (IF), a glycoprotein secreted by the gastric mucosa, is necessary for active absorption of vitamin B₁₂ from gastrointestinal tract. The IF transport mechanism is saturated by 1.5 - 3 mcg of the vitamin. Additional amounts of the vitamin may be absorbed independent of IF by passive diffusion through intestinal wall.

- **Distribution:** Cyanocobalamin is extensively bound to specific plasma proteins called transcobalamins. A small amount may be free or loosely bound. It is distributed into liver, bone marrow and other tissues including placenta. Total body stores are estimated to range 1 - 11 mg, with an average of 5 mg, and mainly stored in the liver.

- **Elimination:** Cyanocobalamin is excreted in bile, part of a dose is excreted in urine, most of it in the first 8 hours. The daily turnover rate of the vitamin is 0.05 - 0.2% of the total body stores.

INDICATIONS :

Mononeuropathies and polyneuropathies eg. diabetic, alcoholic and toxic neuropathies.

Neuritis and neuralgia especially cervical syndrome, shoulder-arm syndrome, lumbago sciatica, root irritation due to degenerative changes of the vertebral column. 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.

WARNING AND PRECAUTION :

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.

PREGNANCY AND LACTATION :

Vitamin B₁

Pregnancy: The possibility of fetal harm appears remote; however, use during pregnancy only if clearly needed.

Lactation: It is not known whether this drug is excreted in breast milk. Use with caution in nursing women.

Vitamin B₆

Pregnancy and Lactation: Pyridoxine requirements are increased during pregnancy and lactation. Use doses in excess of the RDA for lactating female with caution.

Vitamin B₁₂

Pregnancy: Studies have not been done in either animals or humans. Problems in humans have not been documented with intake of normal daily requirements.

Lactation: Vitamin B₁₂ is excreted in breast milk; however, problems in humans have not been documented with intake of normal daily requirement.

STORAGE :

Store at temperature not exceeding 30°C. Protect from light and moisture.

The shelf-life period is 3 years.

SUPPLY :

Pack of 50x10 tablets.

Pack of 10x10 tablets.

Manufactured by
BIOLAB CO., LTD.

625 Soi 7A Bangpoo Industrial Estate, Sukhumvit Road,
 Moo 4, Prakasa, Muang, Samutprakarn 10280, Thailand

Date of revision : 23/08/18

EET 041/B

<p>Note :</p> <p>ห้ามรับประทานร่วมกับเครื่องดื่มที่มีแอลกอฮอล์ ห้ามรับประทานร่วมกับยาที่มีฤทธิ์กดประสาท ห้ามรับประทานร่วมกับยาที่มีฤทธิ์กระตุ้นประสาท</p>		<p>Final Artwork Revision : A</p>	
<p>Code : EET041/B</p>		<p>Draft Revision : 3</p>	
<p>Name : AW_LEAFLET_VIBEE TAB NEW MAL.ai</p>		<p>Final Artwork Revision : A</p>	
<p>Remark :</p>		<p>Signature</p> <p>.....</p> <p>Date</p> <p>.....</p>	
<p>Design by</p> <p>.....</p> <p>Signature</p> <p>.....</p> <p>Date</p> <p>.....</p>		<p>Review by</p> <p>.....</p> <p>Signature</p> <p>.....</p> <p>Date</p> <p>.....</p>	
<p>Approved by</p> <p>.....</p> <p>Signature</p> <p>.....</p> <p>Date</p> <p>.....</p>		<p>Specification</p> <p>Size : 110 x 290 MM. (+/- 3 MM.)</p> <p>Color : พิมพ์ 1 สี คือ สีดำ</p> <p>Material : ใช้กระดาษพิมพ์น้ำหนัก 55 แกรม</p> <p>Other :</p>	

F-QP-GE-011