

THIAMINE MONONITRATE + PYRIDOXINE HYDROCHLORIDE + CYANOCOBALAMIN

BEE-ALL[®]

100 mg / 200 mg / 200 mcg Film-Coated Tablet
Vitamins

FORMULATION :

Each film-coated tablet contains :

Pyridoxine Hydrochloride (Vitamin B6)	200 mg
Thiamine Mononitrate (Vitamin B1)	100 mg
Cyanocobalamin (Vitamin B12)	200 mcg

PRODUCT DESCRIPTION :

Each film-coated tablet contains Vitamin B6 (Pyridoxine Hydrochloride) 200 mg, Vitamin B1 (Thiamine Mononitrate) 100 mg, and Vitamin B12 (Cyanocobalamin) 200 mcg.

It also contains the following excipients : Lactose, Polyvidone (PVP), Microcrystalline Cellulose, Gelatine 250 Bloom, Croscarmellose Sodium, Sodium Starch Glycolate, Magnesium Stearate, Talc, Ethanol, Purified Water, Dichloromethane, FDC Red No. 3 Al-Lake, FDC Red No. 40 Al-Lake, Opadry, and Opaglos.

PHARMACOLOGY :

Mechanism of Action :

Bee-All[®] Tablet is a combination of 3 essential neurotropic vitamins (B1, B6 and B12) in high dosage.

Vitamins B1, B6 and B12 are of special importance for the metabolism in the peripheral and central nervous system. Their effect on the regeneration of nerves has been shown in various investigations using the vitamins individually and in combination.

Vitamin B1 plays an important role in major metabolic processes. Vitamin B6 has an analgesic effect. Vitamin B12 ensures blood cell formation and prevents degenerative processes of the nervous system.

Both the individual function and the beneficial biochemical links between the 3 vitamins justify their combined use.

INDICATIONS :

Neurological and other disorders associated with disturbance of the metabolic functions influenced by B-complex vitamins, including diabetic polyneuropathy, alcoholic peripheral neuritis and post-influenzal neuropathies.

For the treatment of neuritis and neuralgias of the spinal nerves, especially facial paresis, cervical syndrome, low back pain, ischialgia.

DOSAGE AND ROUTE OF ADMINISTRATION :

Dosage :

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

The duration of the treatment is determined by the physician.

Administration :

Swallow without chewing with a little liquid with or after meals.

CONTRAINDICATIONS :

Hypersensitivity to any of the active or excipients of Bee-All[®] Tablet (see section **PRODUCT DESCRIPTION**).

Use in children : Bee-All[®] Tablet and Injection are not suitable for the treatment of children due to the high content of active ingredients.

SPECIAL PRECAUTIONS :

In the literature, neuropathies are described under long-term intake (6 - 12 months) of more than 50 mg mean daily dose of vitamin B6. Therefore, under long-term treatment regular monitoring is recommended.

Bee-All[®] Tablet contains lactose and sucrose, therefore its use is not recommended in patients with intolerance to some sugars (in other word rare hereditary galactose or fructose intolerance, glucose-galactose malabsorption, Lapp lactase deficiency or sucrose-isomaltase insufficiency).

PREGNANCY AND LACTATION :

No risks have become known associated with the use of Bee-All® Tablet during pregnancy at the recommended dosage.

Vitamins B1, B6 and B12 are secreted into human breast milk, but risks of overdose for the infant are not known. In individual cases, high doses of vitamin B6 in other word more than 600 mg daily may inhibit the production of breast milk.

DRUG INTERACTIONS :

Levodopa (L-Dopa) : The effect of L-dopa may be reduced when vitamin B6 is administered concomitantly.

Pyridoxine-Antagonists eg, Isoniazid (INH), Cycloserine, Penicillamine, Hydralazine : The efficacy of vitamin B6 (Pyridoxine) may be decreased.

Loop Diuretics eg, Furosemide : In long-term use, the blood level of thiamine may be reduced.

ADVERSE DRUG REACTIONS :

Hypersensitivity reactions to vitamin B1 or B12 eg, sweating, tachycardia (rapid heartbeat) and skin reactions with itching and urticaria may occur. Gastrointestinal complaints eg, nausea, vomiting, diarrhoea or abdominal pain may occur.

OVERDOSE :

Prolonged overdose of vitamin B6 in other word for more than 2 months and more than 1 g per day, may lead to neurotoxic effects.

STORAGE CONDITION :

Store at temperatures not exceeding 30°C.

PACKAGING AVAILABLE (PACK SIZE) :

Alu/clear PVC blister pack of 10's (Box of 100's)

CAUTIONS :

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

ADR REPORTING :

For suspected adverse drug reaction, report to the FDA : www.fda.gov.ph

REGISTRATION NUMBER :

DR-XY37831

DATE OF FIRST AUTHORIZATION :

26 April 2010

DATE OF REVISION OF PACKAGE INSERT :

January 2017

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER :

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