

**Thiamine Mononitrate (Vitamin B₁)
Pyridoxine Hydrochloride (Vitamin B₆)
Cyanocobalamin (Vitamin B₁₂)**

100 mg/5 mg/50 mcg Tablet

VITAMIN

Description of the product

Pink to brownish-pink to pale yellow brown tablet scored on one side and plain on the other side.

What is in the medicine?

This product contains B-complex vitamins (vitamins B₁, B₆, B₁₂). These nutrients are required for normal nerve function and are used as adjunct in the management of neuromuscular pain. B-complex vitamins have the following neuromuscular functions/effects:

NUTRIENTS	NEUROMUSCULAR FUNCTION
Thiamine (B ₁)	Involved in the production and release of acetylcholine, a neurotransmitter required in conveying signals between cells.
Pyridoxine (B ₆)	Required in the formation of neurotransmitter such as serotonin, gamma amino butyric acid (GABA), dopamine, and epinephrine to facilitate normal nervous system function
Cyanocobalamin (B ₁₂)	Required for the synthesis of myelin, the white sheath that surrounds nerve fibers

Vitamin B₁. Small amounts of thiamine are well absorbed from the gastrointestinal tract after oral doses, but the absorption of doses larger than about 5 mg is limited. It is also rapidly absorbed on intramuscular injection. It is widely distributed to most body tissues, and appears in breast milk. Within the cell, thiamine is mostly present as the diphosphate. Thiamine is not stored to any appreciable extent in the body and amounts in excess of the body's requirements are excreted in the urine unchanged or as metabolites.

Vitamin B₆. Pyridoxine, pyridoxal, and pyridoxamine are readily absorbed from the gastrointestinal tract after oral doses and are converted to the active forms pyridoxal phosphate and pyridoxamine phosphate. They are stored mainly in the liver where there is oxidation to 4-pyridoxic acid and other inactive metabolites which are excreted in the urine. As the dose increases, proportionally greater amounts are excreted unchanged in the urine. Pyridoxal crosses the placenta and is distributed into breast milk.

Vitamin B₁₂. Substances bind to intrinsic factor, a glycoprotein secreted by the gastric mucosa, and are then actively absorbed from the gastrointestinal tract. Absorption is impaired in patients with an absence of intrinsic factor, with a malabsorption syndrome or with disease or abnormality of the gut, or after gastrectomy. Absorption from the gastrointestinal tract can also occur by passive diffusion; little of the vitamin present in food is absorbed in this manner although the process becomes increasingly important with larger amounts such as those used therapeutically. After intranasal dosage, peak plasma concentrations of cyanocobalamin have been reached in 1 to 2 hours. The bioavailability of the intranasal preparation is about 7 to 11 % of the intramuscular injection. Vitamin B₁₂ is extensively bound to specific plasma proteins called transcobalamins; transcobalamin II appears to be involved in the rapid transport of the cobalamins to tissues.

Strength of the medicine?

Each tablet contains:
 Thiamine Mononitrate (Vit. B₁), USP100 mg
 Pyridoxine HCl (Vit. B₆), USP5 mg
 Cyanocobalamin (Vit. B₁₂), USP50 mcg

Vitamin B₁₂ is stored in the liver, excreted in the bile, and undergoes extensive enterohepatic recycling; part of a dose is excreted in the urine, most of it in the first 8 hours; urinary excretion, however, accounts for only a small fraction in the reduction of total body stores acquired by dietary means. Vitamin B₁₂ diffuses across the placenta and also appears in breast milk.

How much and how often should you use this medicine?

One (1) to two (2) tablets daily.
 Or as prescribed by a physician.

What is this medicine used for?

Neuritis, neuralgia, polyneuritis, lumbago, cervical and shoulder-arm syndrome, rheumatic pains, herpes zoster, alcoholism, cardiac disorders, diabetic neuropathy, encephalopathies, iatrogenic complications arising from INH, reserpine and phenothiazine therapy.
 Vitamin B deficiencies.

When should you not take this medicine?

In patients known to be hypersensitive to any of its content.

Undesirable Effects

Thiamine Mononitrate (Vit. B₁)

Adverse effects with thiamine are rare, but hypersensitivity reactions have occurred. These reactions have ranged in severity from very mild to, very rarely, fatal anaphylactic shock.

Pyridoxine Hydrochloride (Vit. B₆)

Long-term use of large doses of pyridoxine is associated with the development of severe peripheral neuropathies; the dose at which these occur is controversial. Pyridoxine reduces the effects of levodopa, but this does not occur if a dopa decarboxylase inhibitor is also given. Pyridoxine reduces the activity of alitretamine. It has also been reported to decrease serum concentrations of phenobarbital and phenytoin. Many drugs may increase the requirements for pyridoxine; such drugs include hydralazine, isoniazid, penicillamine, and oral contraceptives.

Cyanocobalamin (Vit. B₁₂)

Allergic hypersensitivity reactions have occurred rarely after parenteral doses of the vitamin B₁₂ compounds cyanocobalamin.

Care that should be taken when taking this medicine?

Cyanocobalamin (Vitamin B₁₂) should not be given to patients with suspected vitamin B₁₂ deficiency without first confirming the diagnosis. Regular monitoring of the blood is advisable. Administration of doses greater than 10 µg daily may produce a haematological response in patients with folate deficiency; indiscriminate use may mask the precise diagnosis. Conversely, folate may mask vitamin B₁₂ deficiency.

ADR Reporting Statement

"For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph"
 Seek medical attention immediately at the first sign of any adverse drug reaction.

Availability

Blister pack x 10's (Box of 100's)

How should you keep this medicine?

Store at temperatures not exceeding 30°C.

Registration Number

DRP-1458

Date of Authorization / Renewal

December 18, 2010

Date of Revision of PIL

JULY 2021



170.0 mm

105.0 mm

**Insert Required size:
170 mm x 105 mm
UNFOLDED**