

# VITAMINS B1 + B6 + B12

Rx

## MEGANERV™ 1000

500 mg/250 mg/1 mg Tablet

### Vitamin

#### FORMULATION:

Each tablet contains:

Thiamine Hydrochloride (Vitamin B1), USP .....	500 mg
Pyridoxine Hydrochloride (Vitamin B6) .....	250 mg
Cyanocobalamin (Vitamin B12) .....	1 mg (eq. to 1000 mcg)

#### DESCRIPTION:

Meganerv™ 1000 tablet is a blue, round, biconvex film-coated tablet plain on both sides.

Vitamins B1 + B6 + B12 (**MEGANERV™ 1000**) tablet is a high potency combination of the neurotropic vitamins B1 + B6 + B12. This neurotropic formulation derives its properties from the complementary actions of its three active constituents which makes it suitable for the management of neuropathic conditions.

Vitamins B1 + B6 + B12 (**MEGANERV™ 1000**) tablet is coated with a single film integument which masks the unpleasant tastes of its constituted ingredients. Moreover, this film coat protects its active components from possible loss of potency caused by light and other atmospheric degradative factors.

#### PHARMACODYNAMICS AND PHARMACOKINETICS:

Following oral administration, thiamine is absorbed from the gastrointestinal tract and is widely distributed to most body tissues. Thiamine is not stored in the body and amounts in excess of the body's requirements are excreted in the urine as unchanged thiamine or as metabolites.

Pyridoxine is readily absorbed from the gastrointestinal tract. It is converted to the active form pyridoxal phosphate and is stored mainly in the liver. Amounts in excess of the body's requirements are excreted unchanged in the urine. Pyridoxal diffuses across the placenta and appears in breast milk.

Vitamin B12 compounds which bind to the intrinsic factor, a glycoprotein secreted by the gastric mucosa, are actively absorbed from the gastrointestinal tract. Little amount is absorbed by passive diffusion but the process becomes increasingly important with larger or therapeutic amounts.

Vitamin B12 is stored in the liver and excreted in the bile. Part of a dose is excreted in the urine. Vitamin B12 diffuses across the placenta and is also distributed into breast milk.

#### INDICATIONS:

Vitamins B1 + B6 + B12 (**MEGANERV™ 1000**) tablet is indicated in the following conditions and disorders:

- Painful neurological manifestations including neuritis, polyneuritis, lumbago, ischialgia, sciatica, cervical and shoulder-arm syndrome.
- Neuropathies caused by certain disease states such as diabetes and cardiac disorders.

- Alcoholic neuropathy; iatrogenic complications arising from isoniazid, reserpine and phenothiazine therapy; other drug induced neuropathies.
- Hyperemesis gravidarum; neuropathic changes during pregnancy.

#### **DOSAGE AND ADMINISTRATION:**

- For therapeutic use, 2-4 tablets of Vitamins B1 + B6 + B12 (**MEGANERV™ 1000**) should be administered daily until acute symptoms subside. Chronic cases may require longer therapy.
- For prophylactic administration when diseases or drugs are likely to lead to neurological complications, the recommended dosage is 1 - 2 tablets daily.

#### **CONTRAINDICATIONS/PRECAUTIONS/WARNINGS:**

Contraindicated in patients with history of hypersensitivity to the components.

Patients who are hypersensitive to cyanocobalamin injections may be able to take oral cyanocobalamins.

If possible, Vitamin B12 should not be given to patients with suspected vitamin B12 deficiency without first confirming the diagnosis. Use of cyanocobalamin in doses greater than 10mcg daily may produce a hematological response in patients with folate deficiency. Indiscriminate use may mask the precise diagnosis. Conversely, folate may mask vitamin B12 deficiency. Regular monitoring of blood is advisable.

Cyanocobalamin should not be used for Leber's disease or tobacco amblyopia since these optic neuropathies may degenerate further.

#### **PREGNANCY AND LACTATION:**

Vitamin B1, B6 and B12 can be given safely for pregnant and lactating women.

Though some have expressed concern over inhibition of breast milk secretion by pyridoxine, others have cautioned that pyridoxine deficiency may cause seizures in the neonate.

#### **ADVERSE DRUG REACTIONS:**

Adverse effects seldom occur after oral administration of thiamine and cyanocobalamin, but hypersensitivity reactions have been reported after parenteral administration. Hypersensitivity reactions to thiamine ranged from very mild to very rarely, anaphylactic shock. Hypersensitivity reactions have also occurred rarely following oral administration of cyanocobalamin. These include skin reactions such as rash, itching and anaphylaxis.

Nevertheless, it must be stressed that hypersensitivity to vitamin B1 is very rare when given orally and is encountered more often only when given by intravenous injection.

Other adverse effects reported with cyanocobalamin include gastrointestinal disturbances, fever, chills, hot flushing, dizziness, malaise, acneiform and bullous eruptions, and tremor.

Long-term (2 to 40 months) use of large doses of pyridoxine (2 to 6 g daily) is associated with the development of severe peripheral neuropathies.

#### **DRUG INTERACTIONS:**

Drugs that increase the requirements for pyridoxine include hydralazine, isoniazid, penicillamine and oral contraceptives. Pyridoxine reduces the activity of alitretamine and decreases serum concentrations of phenobarbital and phenytoin.

Neomycin, aminosalicylic acid (ASA), histamine-2 receptor antagonists, omeprazole and colchicine may reduce the absorption of vitamin B12 from the gastrointestinal tract.

Oral contraceptives may reduce serum concentrations of vitamin B12.

Though unlikely to be of clinical significance, many interactions of vitamin B12 should be taken into account when performing assays for blood concentration.

**OVERDOSAGE AND TREATMENT:**

No cases of Vitamin B1 overdose have been reported. Vitamin B6 overdose is rare. Two cases that caused central nervous system toxicity have been reported. Overdose of Vitamin B12 is also rare. Although an overdose is highly unlikely, call the doctor right away if you have any reason to suspect that one has occurred.

**AVAILABILITY:**

Aluminum - OPA/Alu/PVC Blister Pack x 10's (Box of 50's).

**CAUTION:**

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

**DR-XY24082**

**STORE AT TEMPERATURES NOT EXCEEDING 30°C.  
PROTECT FROM LIGHT.**

For suspected adverse drug reaction, Report to the FDA: [www.fda.gov.ph](http://www.fda.gov.ph)

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