

THIAMINE MONONITRATE(Vit. B1)
PYRIDOXINE HCl (Vit. B6)
CYANOCOBALAMIN (Vit. B12)

Rx

MEGANERV™300
300 mg/ 100 mg/ 100 mcg Capsule

VITAMIN

FORMULATION:

Each capsule contains:
Thiamine Mononitrate (Vitamin B1).....300 mg
Pyridoxine Hydrochloride (Vitamin B6)100 mg
Cyanocobalamin (Vitamin B12)100 mcg

PRODUCT DESCRIPTION:

Vitamins B1 + B6 + B12 (MEGANERV™ 300 Capsule) is a light pink powder contained in a capsule with a light green body and dark green cap.

Vitamins B1 + B6 + B12 (MEGANERV™ 300 Capsule) is a high potency formulation of the three neurotropic B vitamins, Thiamine Mononitrate (Vitamin B1), Pyridoxine Hydrochloride (Vitamin B6) and Cyanocobalamin (Vitamin B12). This fortified combination of the major B-complex vitamins is specifically valuable in the comprehensive management of neuropathies associated with various conditions.

PHARMACODYNAMICS AND PHARMACOKINETICS:

Normal cellular activities depend on the availability of the biochemical energy derived mainly from the food nutrients. In the metabolic systems of the body, the breakdown products of carbohydrates, fats and proteins must be acted upon by enzymes together with their co-enzymes, primarily vitamins B1, B6 and B12, in order that the processes by which these substrates are further bio-transformed and utilized may continue. Vitamins B1, B6 and B12 stimulate the various metabolic processes of the body which produce the energy needed to fuel the cellular activities, specifically the physiologic activities of the nervous system. As the well-known actions of vitamins B1, B6 and B12 are directed towards the central nervous system (CNS), the purported actions of high doses of these major B vitamins are directed towards the CNS.

Vitamins B1 + B6 + B12 (MEGANERV™ 300 Capsule) has sufficient concentration of B1, Thiamine Mononitrate. Thiamine Mononitrate, as a co-enzyme of carbohydrate metabolism, ensures the efficient production of energy and other metabolites such as ribose, a major component of DNA and RNA. Glucose provides the basic nutritional needs of the nervous system. The cells of the nervous system depend entirely on glucose as its energy source. Independent of its co-enzyme function, Thiamine acts as a modulator in the neuromuscular transmission of impulses.

Thiamine Mononitrate (Vitamin B1) is well absorbed from the gastrointestinal tract after oral doses, but the absorption of doses larger than about 5mg is limited. Thiamine is widely distributed to most body tissues, and appears in breast milk. 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.

Vitamins B1 + B6 + B12 (MEGANERV™ 300 Capsule), with its high concentration of Pyridoxine hydrochloride, is involved in several metabolic transformations of amino acids for tissue building and repair and in the biosynthesis of certain compounds such as neurotransmitters and blood elements needed for hematopoiesis.

Pyridoxine (Vitamin B6) is readily absorbed from the gastrointestinal tract after oral doses and is converted to the active forms, pyridoxal phosphate and pyridoxamine phosphate. Pyridoxine is 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 the breast milk.

Vitamins B1 + B6 + B12 (MEGANERV™ 300 Capsule) contains a substantial amount of cyanocobalamin, a co-enzyme which promotes metabolism of nucleic acids, fats and proteins. Therefore, vitamin B12 is necessary in the formation of new cells and in the repair of nerve tissues.

Cyanocobalamin (Vitamin B12) binds to the intrinsic factor, a glycoprotein secreted by the gastric mucosa and is 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. Cyanocobalamin is extensively bound to specific plasma proteins called transcobalamins; transcobalamin II appears to be involved in the rapid transport of the cobalamins to tissues. Cyanocobalamin is stored in the liver, excreted in the bile and undergoes extensive enterohepatic recycling and part of a dose is excreted in the urine. Vitamin B12 diffuses across the placenta and also appears in breast milk.

The high amounts of B1, B6 and B12 in MEGANERV™ 300 Capsule serve to ensure the optimum nutrition of the neurons thereby stimulating nervous system functions.

INDICATIONS:

The therapeutic Vitamins B1 + B6 + B12 (MEGANERV™ 300 Capsule) act in close functional relationship to provide clinical response in the following disorders:

- Painful neurological manifestations such as neuritis, polyneuritis, neuralgia, 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 (INH), reserpine and phenothiazine therapy; other drug-induced neuropathies.
- Hyperemesis gravidarum; neuropathic changes during pregnancy.

DOSAGE AND ADMINISTRATION:

For therapeutic use, 2-4 capsules should be administered daily. Chronic cases may require longer therapy which the physician will have to adjust depending on the needs of the patient. For prophylactic administration when diseases or drugs are likely to lead to neurological complications, 1-2 capsules daily are recommended.

CONTRAINDICATIONS/PRECAUTIONS/WARNINGS:

Vitamins B1 + B6 + B12 (MEGANERV™ 300 Capsule) is contraindicated in patients with history of hypersensitivity to the components.

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

If possible, Vitamins B1 + B6 + B12 (MEGANERV™ 300 Capsule) 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.

PREGNANCY AND LACTATION:

Vitamins B1 + B6 + 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:

Long-term use of large doses of pyridoxine is associated with the development of severe peripheral neuropathies.

Hypersensitivity reactions have occurred rarely with the use of cyanocobalamin and thiamine. These include skin reactions such as rash, itching and anaphylaxis. Other adverse effects reported with cyanocobalamin includes gastrointestinal disturbances, fever, chills, hot flushing, dizziness, malaise, acneiform and bullous eruptions and tremor. Cyanocobalamin should not be used for Leber's disease or tobacco amblyopia since these optic neuropathies may degenerate further.

DRUG INTERACTIONS:

Drugs that increase the requirements for pyridoxine include hydralazine, isoniazid, penicillamine and oral contraceptives. Pyridoxine reduces the activity of alprazolam and decreases serum concentrations of phenobarbital and phenytoin. Neomycin, aminosalicylic acid, histamine H2-antagonists, omeprazole and colchicine may reduce the absorption of vitamin B12 from the gastrointestinal tract. Parenteral chloramphenicol may attenuate the effect of vitamin B12 in anemia.

OVERDOSE 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 rare too. Although an overdose is highly unlikely, call the doctor right away if you have any reason to suspect that one has occurred.

AVAILABILITY:

Strip Foil x 4's (Box of 100's)

CAUTION:

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

DR-XY20243

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

PROTECT FROM LIGHT

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

Manufactured for:

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