THIAMINE HCl
PYRIDOXINE HCl
CYANOCOBALAMIN

POLYNERV ™ 250

250 mg/250 mg/1 mg Film-coated Tablet

VITAMIN

FORMULATION:
Each film-coated tablet contains:
Thiamine Hydrochloride (Vitamin B1) ..... 250 mg
Pyridoxine Hydrochloride (Vitamin B6) ..... 250 mg
Cyanocobalamin (Vitamin B12) ..... 1 mg (eq. to 1,000 mcg)

DESCRIPTION:
(Vitamins B1, B6 and B12) POLYNERV TM 250 is a high potency formulation of the neurotropic vitamins B1, B6 and B12. This fortified combination of the most essential B vitamins, is a valuable adjuvant or support in the comprehensive management of neural disorders and certain diseases associated with painful neurologic manifestations.

(Vitamins B1, B6 and B12) POLYNERV TM 250 is useful in the prevention and treatment of vitamin B deficiencies arising from poor dietary intake, chronic alcoholism, impaired vitamin B absorption (e.g., excessive vomiting, prolonged diarrhea, antibiotic therapy) and intake of certain drugs which interfere with the utilization of B vitamins (i.e., isoniazid, estrogen, phenothiazine).

(Vitamins B1, B6 and B12) POLYNERV TM 250 tablet is coated with a single layer of film integument which masks the unpleasant taste of its constituted ingredients and also gives the tablet a delectable appearance. Moreover, this film coat protects its active components from possible loss of potency caused by light and other atmospheric degradative factors.

PHARMACODYNAMICS AND PHARMACOKINETICS:
The neurotropic agents, Vitamins B1, B6 and B12 activate specific biochemical pathways involved in nervous system physiology.

Normal cellular activities depend on the availability of the biochemical energy derived mainly from the metabolism of food nutrients. In the metabolic systems of the body, the breakdown products of carbohydrates, fats and proteins are acted upon by enzymes together with their coenzymes (primarily vitamins B1, B6 and B12) in order that the cellular reactions by which these nutrients are further bio-transformed and utilized may continue. Vitamins B1, B6 and B12 stimulate the various metabolic processes which produce the energy needed to fuel the cellular activities of the body, specifically the physiologic activities of the nervous system.

Thiamine (Vitamin B1) functions as a coenzyme, operating as a co-carboxylase in various reactions of glucose metabolism (i.e., decarboxylation of pyruvic acid and other alpha-keto acids leading to synthesis of ATP). Thiamine enhances production of energy from glucose and storage of energy as fat, making energy available to support the normal cellular processes.

Thiamine, as coenzyme of glucose metabolism, ensures that energy is available for the vital organs of the body to do their work. The muscle cells of the heart, blood vessels, and the secretory glands of the gastrointestinal tract depend on the energy derived from metabolism of glucose. Vitamin B1 helps improve muscle tone of the intestine, stomach, heart and blood vessels. Without sufficient energy, the muscles of the heart and blood vessel walls dilate leading to fluid accumulation. The deficiency of thiamine results in certain abnormalities affecting the cardiovascular, gastrointestinal and nervous systems of the body.

Pyridoxine (Vitamin B6) participates in many cellular reactions of lipid and amino acid metabolism (i.e., transamination and decarboxylation reactions). The active form of B6, pyridoxal phosphate, acts as a coenzyme in several metabolic transformations of amino acids which are in turn needed for tissue building and in the synthesis of certain compounds and blood elements. Vitamin B6 is required in the synthesis of delta-aminolevulinic acid, the precursor necessary for the formation of the hemoglobin molecule.

Vitamins B1, B6, B12 (Polynerv 250) tablet contains high amounts of Cyanocobalamin (Vitamin B12) which acts as coenzyme involved in several metabolic pathways (i.e., conversion of methyl-coA to succinyl-coA and fatty acid synthesis). The most important action of vitamin B12 is to act as a coenzyme of nucleic acid metabolism, reducing ribonucleotides to deoxyribonucleotides, a step that is essential in the replication of genes and formation of new cells. Vitamin B12 is also an important cofactor in the formation and maturation of red blood cells in the bone marrow. The deficiency of vitamin B12 results in megaloblastic anemia.

Following oral administration, thiamine is absorbed from the gastrointestinal tract and is widely distributed to most body tissues and appears in breast milk. Thiamine is mostly present within the cells as a diphosphate. 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.

After oral administration, pyridoxine is readily absorbed from the gastrointestinal tract. It is converted to its active form pyridoxal phosphate and is stored mainly in the liver. Proportionally greater amounts are excreted unchanged in the urine as the dose increases. Pyridoxal diffuses across the placenta and appears in breast milk.

Vitamin B12 compounds, which initially bind to the intrinsic factor, a glycoprotein secreted by the gastric mucosa, are then 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 extensively bound to transcobalamin, a plasma protein. 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:
For the prevention and treatment of Vitamin B deficiencies.

DOSAGE AND ADMINISTRATION:
For therapeutic use, 2-4 tablets of (Vitamins B1, B6 and B12) POLYNERV TM 250 should be administered daily until acute symptoms subside. Chronic cases may require longer therapy.

For prophylactic administration when disease or drugs are likely to lead to neurological complications, the recommended dosage is 1-2 tablets daily or as prescribed by the physician.

CONTRAINDICATIONS/PRECAUTIONS/WARNING:
Contraindicated in patients with history of hypersensitivity to the components. Cyanocobalamin should not be given to patients with suspected vitamin B12 deficiency without confirmation of the diagnosis. The vitamins in (Vitamins B1 + B6 + B12) POLYNERV TM 250 tablet are non-toxic even in high doses and usually no adverse or after effects occur. However, sensitivity to Vitamin B1 may sometimes be encountered. Sensitivity may occur if administration at prolonged intervals is irregular or if the initial dose is low and is suddenly increased. Liver dysfunction also seems to predispose patients to hypersensitivity reactions. Nevertheless, it must be emphasized that hypersensitivity to Vitamin B1 is very rare when given orally and is encountered more often only when given by intravenous injection.

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 occurred rarely following oral administration of cyanocobalamin.

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

OVERDOSE AND TREATMENT:
No cases of thiamine overdose have been reported.
Vit B6 overdose is rare. Two cases that caused central nervous system toxicity (see serious side effects) have been reported. Overdose of Vit B12 is rare, too. Although an overdose is highly unlikely, call your doctor right away if you have any reason to suspect that one has occurred.

AVAILABILITY:
Alu-alu blister Pack x 10's (Box of 100's)

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

STORE AT TEMPERATURES NOT EXCEEDING 30^{O}C.

PROTECT FROM LIGHT.

For suspected Adverse Drug Reaction, Report to the FDA: www.fda.gov.ph

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Pharma Nutria

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