Rx

Thiamine Mononitrate (Vitamin B_1) Pyridoxine Hydrochloride (Vitamin B_6) Cyanocobalamin (Vitamin B_{12})

MEDINERV FORTE

300 mg/100 mg/100 mcg Capsule
VITAMINS

PRODUCT DESCRIPTION
Encapsulated in hard black/red gelatin capsule containing white to off-white powder.

FORMULATION
Each capsule contains:

Thiamine Mononitrate (Vit. B_1), USP	300 mg
Pyridoxine HCl (Vit. B_6), USP	100 mg
Cyanocobalamin(Vit. B_{12}), USP	100 mcg

PHARMACODYNAMICS
This product contains B-complex vitamins (vitamins B_1, B_6, B_{12}). 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, aneurotransmitter 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 sorrounds nerve fibers.

PHARMACOKINETICS
Vitamin B_1. 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 B_6. 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 B_{12}. 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 abscence 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 peparation is about 7 to 11 % of the intramuscular injection. Vitamin B_{12} is extensively bound to specific plasma proteins called transcobalamins; transcobalamin II appears to be involved in the rapid transport of the cobalamins to tissues.

INDICATIONS
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.

DOSAGE AND MODE OF ADMINISTRATION:
As prophylaxis:
1-2 capsules daily.

As therapy:
2-4 capsules.
Or as prescribed by a physician.

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

WARNING
Cyanocobalamin (Vitamin B_{12}) should not be given to patients with suspected vitamin B_{12} 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 B_{12} deficiency.

INTERACTIONS
Vitamin B_6. Pyridoxine reduces the effects of levodopa but this does not occur if a dopa decarboxylase inhibitor is also given. Pyridoxine reduces the activity of altretamine. It has also been reported to decrease serum concentrations of phenobarbital and phenytoin. Many drugs may increase the requirements for pyridoxine; such drugs hydrazaline, isoniazid, penicillamine and oral contraceptives.
Vitamin B_{12}. Absorption of vitamin B_{12} from the gastrointestinal tract may be reduced neomycin, aminosalicylic acid, histamine H_2-antagonists, omeprazole, and colchicine. Serum concentrations may be decreased by use of oral contraceptives. Many of these interactions are unlikely to be of clinical significance but should be taken into account when performing assays for blood concentrations. Parenteral chloramphenicol may attenuate the effect of vitamin B_{12} in anaemia.

ADVERSE EFFECTS
Thiamine Mononitrate (Vit. B_1)
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. B_6)
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 altretamine. 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. B_{12})
Allergic hypersensitivity reactions have occurred rarely after parenteral doses of the vitamin B_{12} compounds cyanocobalamin.

OVERDOSE AND TREATMENT
Vitamin B_6. Although vitamin B_6 has generally been considered relatively nontoxic, long term (two months or longer) administration of large (megadose) dosages (usually 2 grams or more daily) of vitamin B_{12} can cause neurogical symptoms manifested as paresthesia (more noticeable at night and limited to the extremities), bone pains (described as lightning, stabbing or shooting like a knifing needle or electric shocks), hyperesthesia (described in burning, pricking, stinging, or itching), muscle weakness (difficulty in running, lifting, climbing stairs and loss of manual dexterity) fasciculation (described as twitching, restlessness or fidgeting), and numbness of the limbs and face.

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

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)

STORAGE CONDITION
Store at temperatures not exceeding 30oC

REGISTRATION NUMBER
DRP-887-02

DATE OF FIRST AUTHORIZATION/ RENEWAL
September 24, 2008

DATE OF REVISION
June 2021

Distributed by:
ALTAMEDICA INCORPORATED
Rm 410, Manila Astral Tower 1330 Taft Ave., Cor. Padre Faura St., Ermita 073, Brgy. 676, Manila, Metro Manila

Manufactured by
JM TOLMANN LABORATORIES, INC.
#65 North Zuzuarregui St., Iloilo, Q.C.