135 mm

210 mm

Martin Dow

Neuromet™ SL (Mecobalamin) Tablets

نیوروومیٹ ایس ایل گولیاں

COMPOSITION

Neuromet™ SL Tablet 500 mcg:
Each sublingual tablet contains:
Mecobalamin, USP..... 500 mcg

Neuromet™ SL Tablet 1000 mcg:
Each sublingual tablet contains:
Mecobalamin, USP..... 1000 mcg

Neuromet™ SL Tablet 2000 mcg:
Each sublingual tablet contains:
Mecobalamin, USP..... 2000 mcg

DESCRIPTION

Mecobalamin, one of the coenzyme forms of vitamin B_{12}, acts as an important cofactor in the activities of B_{12}-dependent methyltransferases. Vitamin B_{12} is a general label for a group of essential biological compounds known as cobalamins. Cobalamins are structurally related to haemoglobin and its deficiency can cause anaemia. The most common form of Vitamin B_{12} is called cyanocobalamin but methyl cobalamin form is vital to protect against neurological diseases and aging.

THERAPEUTIC INDICATIONS

- Peripheral neuropathy (e.g., diabetic, alcoholic, and uremic neuropathy).
- Drug induced neuropathy.
- Neurological disease & aging.
- Symptoms of Vitamin B_{12} deficiency.
- Prolonged inadequate or incorrect nutrition (e.g., strict vegetarian diet).
- Malabsorption due to insufficient production of intrinsic factor.
- Post Gastrectomy vitamin B_{12} deficiency.
- Hyperchromic or Macrocytic or Megaloblastic anemia, Pernicious anemia, Biermer anemia, Addison's anemia.
- Congenital disorders of Vitamin B_{12} transport.

DOSAGE AND ADMINISTRATION

Dosage:
Adult: 500mcg, three times a day or as prescribed by the physician.
The dose can vary based on individual patient factors, such as the severity of the deficiency, underlying medical conditions, and the healthcare provider's clinical judgment.

Method of Administration:

- This medicine may be taken with or without food.
- Sublingual tablets must not be swallowed.
- Under the tongue, the sublingual tablet should be mounted.
- Without chewing, the medicine will be dissolved under the tongue; alter its position to avoid prolonged contact with the same area.

CONTRAINDICATIONS

Hypersensitivity to mecobalamin or other components of the formulation.

WARNINGS AND PRECAUTIONS

- Should not be used over a period of months if there is a lack of satisfactory clinical response to the patients with megaloblastic anemia probably due to vitamin B_{12} deficiency or with peripheral neuropathies.
- Prolonged use is not recommended for patients whose occupation requires the handling of mercury or its compounds.
- The prescribing physician should be notified of the patient's medical history pertaining to Leber's disease, alternate forms of optic nerve impairment, iron or folic acid insufficiency, or hypokalemia.

DRUG INTERACTIONS

- **Cholestyramine:** Cholestyramine may decrease the enterohepatic reabsorption of Mecobalamin.
- **Colchicine:** Colchicine may cause decreased absorption of Mecobalamin.
- **Colestipol:** Colestipol may decrease the enterohepatic reabsorption of Mecobalamin.
- H_2 Blockers (cimetidine, famotidine, nizatidine, ranitidine): Chronic use of H2 blockers may result to decreased absorption of Mecobalamin. They are unlikely to affect the absorption of supplemental B_{12}.
- **Metformin:** Metformin may decrease the absorption of Mecobalamin. This possible effect may be reversed with oral calcium supplementation.
- **Nitrous oxide:** Inhalation of the anesthetic agent nitrous oxide (not to be confused with nitric oxide) can produce a functional deficiency. Nitrous oxide forms a complex with cobalt in Mecobalamin, the cofactor for methionine synthase, resulting in inactivation of the enzyme.
- **Para-amino Salicylic Acid:** Chronic use of the anti-tuberculosis drug may decrease the absorption of Mecobalamin.
- **Potassium chloride:** It has been reported that potassium chloride may decrease the absorption of Mecobalamin.
- **Proton Pump Inhibitors** (**Lansoprazole, omeprazole, pantoprazole, Rabeprazole**): Chronic use of proton pump inhibitors may result in decreased absorption, naturally found in food sources.

PREGNANCY AND LACTATION
Vitamin B_{12} is likely safe when used orally in amounts that do not exceed the recommended dietary allowance (RDA). The RDA for vitamin B_{12} in pregnant women is 2.6 mcg per day and 2.8 mcg during lactation periods.

There is insufficient reliable information available about the safety of consuming greater amounts of Vitamin B_{12} during pregnancy.

ADVERSE EFFECTS
Some of the common adverse effects of Mecobalamin are:

- Nausea
- Vomiting
- Diarrhea
- Loss of appetite
- Headache

Rare but more serious adverse effects include:
- Irregular heartbeat.
- Muscle cramps or weakness.
- Anaphylactoid reaction: Anaphylactic reactions such as decrease in blood pressure or dyspnea may occur. Patient should be monitored after administration of dose.

PHARMACOLOGY
Mechanism of Action:

1. Mecobalamin plays an important role in transmethylation as a coenzyme of methionine synthesis from homocysteine. Mecobalamin is well transported to nerve cell organelles and promotes nucleic acid and protein synthesis.

2. Mecobalamin promotes axonal regeneration. It normalizes axonal skeletal protein transport in sciatic nerve cells from animal models with streptozotocin-induced diabetes mellitus. It exhibits neuropathologically and electrophysiologically inhibitory effects on nerve degeneration in neuropathies induced by drugs eg, adriamycin, acrylamide and vincristine models of axonal degeneration in mice and neuropathies in animals with spontaneous diabetes mellitus.

3. Mecobalamin promotes myelination (phospholipid synthesis). It promotes the synthesis of lecithin, the main constituent of medullary sheath lipid and increases myelination of neurons in animal tissue culture more than cobalamide does.

4. Mecobalamin restores delayed synaptic transmission and diminished neurotransmitters to normal. It restores end-plate potential induction early by increasing fiber excitability in crushed sciatic nerve. In addition, it also normalizes diminished brain tissue levels of acetylcholine in animals fed with a choline-deficient diet.

5. Mecobalamin promotes the maturation and division of erythroblasts, thereby alleviating anemia. It also increases erythrocyte production. Mecobalamin brings about a rapid recovery of diminished red blood cell and hematocrit in vitamin B_{12} deficient animals.

Pharmacokinetics
The absorption of drug through sublingual route is 3 to 10 times greater than oral route. Blood levels of patients indicate that the sublingual mecobalamin becomes available as early as 15 min after administration and is still elevated at 24 hours. It is absorbed through the oral mucosa, which bypasses the need for it to bind with intrinsic factor in the stomach. Eighty percent (80%) of B12 in the plasma is the mecobalamin form. Mecobalamin in the circulation is bound to the plasma proteins transcobalamin I (TCI), transcobalamin II (TCII) and transcobalamin III (TCIII). Approximately 80% of plasma B12 is bound to TCI. TCII is the principal B12 binding protein for the delivery of B12 to cells via specific receptors for TCII. The metabolites produced during mecobalamin metabolism are primarily excreted through the kidneys in the urine (40-90%).

OVERDOSE
Mecobalamin has good tolerability. Treatment is unlikely to be needed in case of overdose.

HOW SUPPLIED:
Presentation
Neurometᵀᴹ SL Tablets 500 mcg: Pack of 3 x 10's tablets
Neurometᵀᴹ SL Tablets 1000 mcg: Pack of 3 x 10's tablets
Neurometᵀᴹ SL Tablets 2000 mcg: Pack of 3 x 10's tablets

Direction for use:
Allow tablets to dissolve under tongue.
Do not chew or swallow the tablet.

Instructions:
Store below 30 ºC.
Protect from light, heat and moisture.
Keep out of the reach of children.

Warning:
Pregnant or breast-feeding women should consult healthcare professional before use.

Nutritional supplement - not for tretment of any disease.

طریقہ استعمال:
گولی کو زبان کے نیچے حل ہونے دیں۔
گولی کو نہ چبائیں اور نہ نگلیں۔

ہدایات:
۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
روشنی، گرمی اور نمی سے محفوظ رکھیں۔
بچوں کی پہنچ سے دور رکھیں۔

نیوٹریشنل سپلیمنٹ ۔۔ یہ پراڈکٹ کسی بیماری کے علاج کے لیے نہیں ہے۔

Manufactured for:
Martin Dow Marker Ltd.
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Company E. No. 0018