Vitamin B12 Methylcobalamin 1000 mcg Sublingual Tablets

Product Summary:

Vitamin B12 absorption decreases with age, so adults 50 years and older may see considerable health benefits through supplementation with B12. Vitamin B12 helps boost metabolism, produce red blood cells and maintain a healthy central nervous system. Vitamin B12 (methylcobalamin) helps control homocysteine levels. High levels of homocysteine may dramatically increase the risk of heart disease and osteoporosis.

Properties/Uses:

The claim as approved by *Natural Health Products Directorate* (NHPD): A factor in the maintenance of good health. Helps the body metabolize fats, proteins and carbohydrates. Helps form red blood cells.

BLOOD

Pharmacology:

Vitamin B12 is a water-soluble vitamin commonly found in meat, dairy products and fortified grain products. Vitamin B12 (methylcobalamin) is the bioavailable form of B12 that is quickly absorbed into the blood stream. B12 is vital for energy production; as it helps the body metabolize carbohydrates, fats and proteins; for nervous system function, as it is needed to produce myelin, the fatty substance that forms a protective sheath around nerves; and to support good cardiovascular function. Its role, as part of a coenzyme, is to help build red blood cells, form DNA (our genetic make-up). Orally, vitamin B12 is used for treating pernicious anemia and preventing and treating vitamin B12 deficiency. It is also used for the prevention of age-related macular degeneration.

Vitamin 12 works with methionine synthase to mediate two crucial intracellular metabolic processes: the synthesis of nucleic acids, which controls growth and cellular division, and secondly, the numerous methylation reactions. Deficiency of cobalamin leads to two well-recognized clinical manifestations, pernicious anemia, also called megaloblastic anemia because the red blood cells are larger than normal, and cobalamin-associated neuropathy in which the spinal cord, brain, optic nerve and peripheral nerves may be affected.[1,2]

An important manifestation of B12 deficiency, and the failed methylation that B12 deficiency brings, is the elevation of plasma homocysteine. Elevated plasma homocysteine is now viewed by many experts as a greater risk factor than elevated cholesterol for developing coronary heart disease.[3] Homocysteine must be methylated to form methionine via B12 or folic acid, or converted to cysteine via vitamin B6. Homocysteine is a natural cellular by-product of methionine metabolism, intended to have a transient existence. Failure to metabolize homocysteine to methionine or cysteine leads to unresolved elevated plasma levels. Homocysteine is cytotoxic to the endothelium and is able to initiate the focal lesions that will become coronary atherosclerosis.[3]

Absorption of vitamin B12 is aided by a gastric intrinsic factor. However, even in the absence of this intrinsic factor, passive absorption of an oral dose is possible, but higher than normal daily doses are required.[4] The current practice is to use injectable cobalamin, and this may be the most judicious initial approach. However, early studies have demonstrated that pernicious anemia, secondary to an inability to synthesize the gastric intrinsic factor, could be controlled with a B12 dosage range of 300 to 1000 mcg per day.[4] One of the most impressive was a three year Swedish study with 64 patients with pernicious anemia and other cobalamin-related pathologies. The patients were treated with 1000 mcg of cobalamin orally. At the end of the study, the patients demonstrated complete normalization of blood levels and liver storage of cobalamine, and complete clinical remission.[4-6]

Absorption may also be diminished simply as a result of growing older, even when some measure of intrinsic factor is present.[3] This is likely to be an important reason in explaining why a significant number of the elder population demonstrate low plasma B12 levels. Older patients at the pharmacy should be encouraged to have their physician assess their B12 status.

Manufactured product information:

Manufacturer:
WN Pharmaceuticals® Ltd.

Size/UPC:
100's 7 77747 10319 5

NPN:
80006939

Expiry Date:
36 months from date of manufacture

Active Ingredient:
Each tablet contains:

Vitamin B12 (Methylcobalamin)..... 1000 mcg

Non-Medicinal Ingredients (in descending order):
Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate.

Appearance:
Light pink speckled bisected round tablet.

Packaging:
175 cc white round bottle with safety seal under a 38 mm white induction sealed cap with vented interior seal and a label applied to the bottle. Lot number and expiry date are printed on the label applied to the exterior of the bottle.

Storage:
Store in a cool, dry place. Protect from light.

Dose:

As per the NHPD monograph for vitamin B12, the recommended maximum daily dose is 1000 mcg.[7]

Directions:

(Adults): Dissolve 1 tablet daily under the tongue or as recommended by a physician.

Caution:

The caution as approved by the *Natural Health Products Directorate* (NHPD): KEEP OUT OF THE REACH OF CHILDREN. STORE AT ROOM TEMPERATURE IN A DARK, DRY PLACE. DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING.

Deficiency Symptoms:

The body can store B12, however a strict vegetarian and/or vegan diet without proper supplementation could lead to a deficiency. The elderly and people with mild to moderate low levels of stomach (gastric) acid may also be at risk of developing B12 deficiency. Vitamin B12 levels decrease with age and can be influenced also by smoking, high alcohol consumption and prescription drugs. Vitamin B12 deficiency can lead to anemia and neurological symptoms (such as depression and memory loss). Low vitamin B12 levels are also linked to chronic fatigue syndrome.

An important manifestation of B12 deficiency is the elevation of plasma homocysteine. Elevated plasma homocysteine is now viewed by many experts as a greater risk factor than elevated cholesterol for developing coronary heart disease.[3] Elevated homocysteine levels have also been connected to age-related macular degeneration and dementia.[8,9]

Under the right circumstances, supplementing folic acid can mask vitamin B12 depletion. Supplementing folic acid without also supplementing B12 can mask a true B12 depletion allowing neurological damage to proceed unsuspected. It is always recommended that folic acid and vitamin B12 be supplemented together.

Drug Interactions/Contraindications:

Chloramphenicol can delay or interrupt the reticulocyte response to supplemental vitamin B12 in some patients. Monitor blood counts closely.[10]

Some drugs can affect vitamin B12 levels:[10]

- High alcohol consumption can lower vitamin B12 levels.
- Smoking can lower vitamin B12 levels.
- Aminosalicyclic acid can reduce vitamin B12 absorption.
- Potassium supplements can interfere with vitamin B12 absorption.
- Antibiotics can increase excretion of vitamin B12.
- Oral contraceptives: There are conflicting reports of oral contraceptives lowering vitamin B12 levels.
- Colchicine may interfere with the absorption of vitamin B12.
- Cobalt irradiation may decrease GI absorption.
- Metformin can reduce vitamin B12 levels.
- Nitrous oxide inactivates the cobalamin form of vitamin B12.
- Zidovudine (Retrovir or AZT) may interfere with the absorption of vitamin B12.
- Tranquillizers may deplete vitamin B12.[11]
- Dilantin may reduce vitamin B12 absorption.

Toxicity/Adverse Reactions:

The body is able to achieve high blood and tissue levels of vitamin B12 without toxicity.[4]

Allergen Content/Ingredient Sensitivity:

NO	YES
Artificial Colors	Milk Products
Artificial Flavors	
Artificial Sweeteners	
Corn Products	
Egg Products	
Fish	
Gluten	
Hydrolyzed Plant Protein	
Lecithin	
Peanuts	
Preservatives	
Sesame Products	
Shellfish	
Soy Products	
Starch/Modified Starch	
Sulphites	
Tartrazine	
Tree Nuts	
Wheat Products	
Yeast	

NOT ACCEPTABLE FOR THE FOLLOWING DIETARY RESTRICTIONS:

Free of animal products

Kosher

References:

1. Jeffery DR. Nutrition and Diseases of the Nervous System. In: Shills ME, Olson, JA, Shike M, Ross AC (eds). Modern Nutrition in Health and Disease, ninth edition.

2. Weir DG, Scott JM. Vitamin B12 "Cobalamin". In: Shills ME, Olson, JA, Shike M, Ross AC (eds). Modern Nutrition in Health and Disease, ninth edition. Lippincott Williams & Wilkins, New York NY, 1999.

3. McCully K. The Heart Revolution. HarperCollins Publishers, New York NY, 1999.

4. Murray MT. Encyclopedia of Nutritional Supplements. Prima Publishing, Rocklin CA, 1996.

5. Berlin H, Berlin R, Brante G. Oral treatment of pernicious anemia with high doses of vitamin B12 without intrinsic factor, Acta Med Scand 1968;184:247-248.

6. Berlin R, et al. Vitamin B12 body stores during oral and parenteral treatment of pernicious anemia. Acta Med Scand 1978;204:81-84.

7. Health Canada, Vitamin B12 Monograph, Accessed September 13, 2010 [Available from: http://www.hc-sc.gc.ca]

8. Christen WG, Glynn RJ, Chew EJ, Albert CM, Manson JE. Folic acid, pyridoxine, and cyanocobalamin combination treatment and age-related macular degeneration in women: the Women's Antioxidant and Folic Acid Cardiovascular Study. Arch Intern Med. 2009 Feb 23;169(4):335-41

9. Office of the Dietary Supplements, Dietary Supplement Fact Sheet: Vitamin B12, Accessed May 2010 [Available from: http://dietary-supplements.info.nih.gov]

10. Natural Medicine Comprehensive Database (NMCD), Vitamin B12 Monograph, Accessed September 13, 2010 [Available from: http://www.naturaldatabase.com/]

11. Graedon J, Graedon T. Deadly Drug Interactions. St Martin's Griffin, New York NY, 1995.

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