B50 Vitamin B Complex Tablets

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Product Summary:

The B vitamins, along with the related nutrients comprised of folic acid, biotin, pantothenic acid, choline and inositol, are critical for a wide range of biological and metabolic processes, including amino acid, lipid, and carbohydrate metabolism, synthesis of neurotransmitters, regulation of glucose metabolism, formation of red blood cells, cellular metabolism, and maintenance of the structure and function of cell membranes.

Properties/Uses:

The claim as approved by the *Natural Health Products Directorate* (NHPD): For the maintenance of good health. Helps the body metabolize proteins, fats and carbohydrates. A factor in the normal growth and development.

GENERAL HEALTH
& WELLNESS

Pharmacology:

The B vitamins collectively are water soluble vitamins that are important for a wide range of biological processes. Vitamin B1, also known as thiamine, is found in high amounts in the brain and nervous system.[1] Thiamine converts to thiamine diphosphate which is essential for amino acid and glucose metabolism and is an important enzyme co-factor for cellular and metabolic processes including synthesis of neurotransmitters such as acetylcholine and gamma-aminobutyric acid (GABA) in the brain.[1,2] The need for thiamine increases when energy use is increased. Deficiency of thiamine is more likely when certain foods which contain thiaminases (such as raw fish and raw shellfish) or anti-thiamine compounds (such as some teas and betel nut) are eaten frequently. Thiaminases rapidly degrade thiamine during food storage or passage through the gastrointestinal tract.

Vitamin B2, also known as riboflavin, converts to flavin adenine mononucleotide and flavin adenine dinucleotide, which are important coenzymes that participate in oxidation-reduction reactions in numerous metabolic pathways and for energy production.[3,4]

Niacin or Vitamin B3 converts to niacinamide, the amide derivative of niacin, in the body.[5] Nutritionally speaking niacin and niacinamide function the same physiologically and are considered equivalent.[6] Only in pharmacologic doses (typically 1000 mg and higher) do niacin and niacinamide have different activities. At these high doses niacin, but not niacinamide, is able to lower elevated triglycerides and cholesterol.

Niacinamide forms nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP) in the mitochondira, cytoplasm, and other areas of the body.[5] NAD and NADP are involved in numerous metabolic processes. NADP is involved in oxidation-reduction reactions and anabolic reactions, such as the synthesis of fatty acids and cholesterol. NAD is used in catabolic reactions to transfer free energy stored in carbohydrates, fats, and proteins to reduced nicotinamide adenine dinucleotide (NADH), which is used to produce adenosine triphosphate (ATP), the primary form of energy of the cell. NAD and NADP are co-enzymes involved in numerous metabolic processes including glycogenolysis, tissue respiration and lipid metabolism.

Vitamin B6 is a water-soluble B complex vitamin which is present in many foods as three forms, namely pyridoxine, pyridoxal and pyridoxamine.[7] Loss of vitamin B6 is small during food storage and handling but major losses can occur during cooking and processing of food. Vitamin B6 is absorbed well from the gastrointestinal tract and mainly stored in the liver, though pools of vitamin B6 also exist in the muscle, brain, plasma, and erythrocytes.[7,8] When needed vitamin B6 is transported to additional sites in the body.

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Vitamin B6 is converted in the body to pyridoxal phosphate and pyridoxamine phosphate, which are essential coenzymes in the metabolism of certain amino acids, carbohydrates and lipids, in the synthesis of heme and neurotransmitters including GABA, for the processes of gluconeogenesis and glycolysis, and to support immune system function.[7,8]

Vitamin B12, also known as cobalamin, is a water soluble vitamin synthesized by microorganisms.[9] Animals ingest the microorganisms and incorporate vitamin B12 into their flesh, organs, eggs, and milk, which humans then ingest. Plants are meager sources of vitamin B12 and thus vegetarians are at risk of developing vitamin B12 deficiency. Cyanocobalamin, hydroxocobalamin and methylcobalamin are synthetic and equivalent forms of vitamin B12.[10] Vitamin B12 cannot be manufactured by the body and must be supplied in the diet.

Vitamin B12 is irregularly absorbed from the small intestine following oral administration.[10] Dietary vitamin B12 is bound to protein and requires gastric acid and gastric intrinsic factor for proteolysis before absorption can occur. Only about 1% of an oral dose is absorbed without gastric intrinsic factor.[9] After absorption vitamin B12 is distributed to the liver, bone marrow, and other tissues.[10] Extensive stores in the liver prevent deficiency from causing immediate symptoms. In fact, there may be a 5 to 10 year delay between dietary deficiency and onset of symptoms. Due to low absorption following oral administration, parenteral administration is generally required for treatment of pernicious anemia and other vitamin B12 deficiency states.

Vitamin B12 is required for numerous processes including nucleoprotein and myelin synthesis, cell production and growth, the maintenance of erythropoiesis, and for utilization of folate.[10]

Folic acid is a water soluble B complex vitamin also known as vitamin B9.[11] Folic acid is the stable, oxidized form of folate. Folate occurs naturally in food, while the oxidized form, folic acid, is synthetically derived and often found in pharmaceutical products or used to fortify food products.[12]

Folic acid is readily absorbed from the gastrointestinal tract and converted in the liver to its metabolically active form, tetrahydrolic acid which is an important cofactor in the synthesis of purines and thymidylates of nucleic acids and for maintaining normal erythropoiesis.[12] Folic acid reduces elevated plasma homocysteine levels, which is an independent risk factor in the development of cardiovascular disease.

Biotin, sometimes known as vitamin B7, is an essential nutrient required in the diet.[13] It is a required cofactor for five carboxylases, which are required for numerous metabolic pathways and processes, including fatty acid and amino acid metabolism, the Krebs cycle, the citric acid cycle, and glucose regulation. Biotin is modestly water soluble and appears moderately well absorbed in the gastrointestinal tract, with subsequent transportation to the liver and tissues, including the central nervous system and into the placenta and human milk in pregnant and lactating women.

Pantothenic acid is a water soluble B vitamin, sometimes known as vitamin B5.[14] It is readily absorbed from the gastrointestinal tract and widely distributed to body tissues.[15] Pantothenic acid is an essential nutrient that is a component of coenzyme A and required for energy production, acetylation reactions in gluconeogenesis, carbohydrate and lipid metabolism, and in the synthesis of steroid hormones, porphyrins, acetylcholine, leucine, arginine, methionine, and other compounds.[14,15]

Choline is a water soluble essential nutrient that is usually grouped with the B vitamins. It is required for normal function of all cells, especially for the structural integrity and signaling functions of cell membranes.[16] Choline is also required for the synthesis and release of acetylcholine in nerve cells (cholinergic neurotransmission) and lipid transport and metabolism. Most choline in the body is found in phospholipids such as phosphatidylcholine (lecithin) and sphingomyelin. Phosphatidylcholine is the predominant phospholipids found in most cell membranes. Important metabolites of choline include platelet-activating factor, acetylcholine, choline plasmalogens, lysophosphatidylcholine, phosphocholine, glycerophosphocholine, and betaine.

Inositol was once considered a member of the B vitamin group, but later classified as a pseudovitamin. Inosital is a critical nutrient for cellular metabolism and required for production of inositol phosphates and phosphinositides.[17] Similar to choline, inositol is required for synthesis of structural lipids, such as phosphatidylinositol , found in cell membranes. Inositol is also essential for synthesis of numerous cell messengers and signaling molecules, neurotransmitters, and growth factors.

Manufactured product information:

Manufacturer:
WN Pharmaceuticals® Ltd

Size / UPC:
120's 7 77747 10313 3

NPN:
02231626

Expiry Date:
36 months from date of manufacture

Active Ingredients:
Each tablet contains:

Vitamin B1 (thiamine hydrochloride)	50 mg
Vitamin B2 (riboflavin)	50 mg
Niacinamide	50 mg
Vitamin B6 (pyridoxine hydrochloride)	50 mg
Vitamin B12 (cyanocobalamin)	50 mcg
Biotin	50 mcg
Folic Acid (folate)	1 mg
Pantothenic Acid (calcium *d*-pantothenate)	50 mg
Choline (bitartrate)	50 mg
Inositol	50 mg

Non-Medicinal Ingredients (in descending order):
Microcrystalline cellulose, PABA, magnesium stearate, coating (carbohydrate gum, glycerin).

Appearance:
Caplet shaped orange speckled clear coated tablet.

Packaging:
300 cc white round bottle with safety seal under a 45 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:
Preserve in tight, light resistant containers in a cool, dry place.

Dose:

Vitamin B1 (thiamine), RDA:[1]

Infants 1-3 years: 0,5 mg

Children 4-8 years: 0.6 mg

Children 9-13 years: 0.9 mg

Children 14-18 years: 1.0 mg

Adults: 1.0 to 1.1 mg

Pregnant women: 1.4 mg

Lactating women: 1.4 mg

Vitamin B2 (riboflavin), RDA:[3]

Infants 1-3 years: 0,5 mg

Children 4-8 years: 0.6 mg

Children 9-13 years: 0.9 mg

Children 14-18 years: 1.3 mg for males; 1.1 mg for females

Adults: 1.3 mg for males; 1.1 mg for females

Pregnant women: 1.4 mg

Lactating women: 1.6 mg

Vitamin B3 (niacin), given as Niacin Equivalents (1mg niacinamide = 1 mg niacin), RDA:[5]

Infants: 2 to 4 mg

Children 1-3 years: 6 mg

Children 4-8 years: 8 mg

Adolescents 9-13 years: 12 mg

Adolescents 14-18 years: 16 mg for males; 14 mg for females

Adults: 16 mg for males; 14 mg for females

Pregnant women: 18 mg

Lactating women: 17 mg

Vitamin B6 (pyridoxine), RDA:[7]

Infants: 0.1 to 0.3 mg

Children 1-3 years: 0.5 mg

Children 4-8 years: 0.6 mg

Adolescents 9-13 years: 1.0 mg

Adolescents 14-18 years: 1.3 mg for males; 1.2 mg for females

Adults 19-50 years: 1.3 mg

Adults 51 years and over: 1.7 mg for males; 1.5 mg for females

Pregnant women: 1.9 mg

Lactating women: 2.0 mg

Vitamin B12 (cobalamin, equivalent to cyanocobalamin),RDA:[9]

Adults: 2.4 µg

Pregnant and Lactating Women: 2.8 µg

Folic acid (folate), expressed as Dietary Folate Equivalent, RDA:[11]

Infants 0-6 months: 9.4 µg/kg/d (AI)

Infants 7-12 months: 8.8 µg/kg/d (AI)

Children 1-3 years: 150 µg (RDA)

Children 4-8 years: 200 µg (RDA)

Adolescents 9-13 years: 300 µg (RDA)

Adolescents 14-18 years: 400 µg (RDA)

Women of Reproductive Age: 800 µg (RDA)

All other adults: 400 µg (RDA)

Pregnant women: 600 µg (RDA)

Lactating women: 500 µg (RDA)

Biotin,AI:[13]

Infants 0-6 months: 5 µg

Infants 7-12 months: 6 µg

Children 1-3 years: 8 µg

Children 4-8 years: 12 µg

Adolescents 9-13 years: 20 µg

Adolescents 14-18 years: 25 μg

Adults 19-50 years: 30 μg

Pregnant women: 30 μg

Lactating women: 35 μg

Pantothenic Acid, AI:[14]

Infants 0-6 months: 1.7 mg

Infants 7-23 months: 1.8 mg

Children 1-3 years: 2 mg

Children 4-8 years: 3 mg

Adolescents 9-13 years: 4 mg

Adolescents 14-18 years: 5 mg

Adults 19 years and older: 5 mg

Pregnant Women: 6 mg

Lactating Women: 7 mg

Choline, AI:[16]

Infants 0-6 months: 125 mg

Infants 6-12 months: 150 mg

Children 1-3 years: 200 mg

Children 4-8 years: 250 mg

Adolescents 9-13 years: 375 mg

Adolescents 14-18 years: 550 mg for males; 400 mg for females

Adults 19 years and older: 550 mg for males; 425 mg for females

Pregnant Women: 450 mg

Lactating Women: 550 mg

Inositol:

There is no specific daily recommended allowance for inositol, since it is a non-essential factor that our bodies can synthesize.[17]

Directions:

(Adults): 1 tablet daily 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:

Deficiency of B vitamins, singly or as a group, can result in a multitude of physiological problems. Thiamine deficiency causes impairment of metabolic and cellular processes, including impaired production of brain neurotransmitters, impaired amino acid and glucose metabolism, and increased oxidative stress.[1] Impairment of sensory, motor and reflex functions occurs, as well as neurological impairment and a condition known as beri-beri.

Vitamin B2 deficiency is associated with alcoholism, anorexia nervosa, cancer, heart disease, infection, chronic diarrhea, malabsorption syndrome, diabetes and other chronic debilitating diseases. Common symptoms include stomatitis, fissuring of the lips, desquamation of the mucous membranes, redness and scaling of the scrotum, anemia and neuropathy. Vitamin B2 deficiency is usually accompanied by other B vitamin deficiencies and generally does not occur in isolation.[4]

Primary niacin deficiency occurs from inadequate intake of niacin and tryptophan and occurs in areas where maize constitutes a major portion of the diet.[5] Niacin found in maize is bound and not assimilated in the gastrointestinal tract unless it has been treated with alkali, as when tortillas are made. Corn protein is deficient in tryptophan which worsens the niacin deficiency. Protein and the B vitamins are also often deficient when niacin deficiency occurs. Secondary niacin deficiency can occur following diarrhea, alcoholism, or cirrhosis and in certain diseases where tryptophan may be deficient such as carcinoid syndrome and Hartnup disease.[5,6]

Deficiency of niacin causes the common skin, mucous membrane, central nervous system, and gastrointestinal symptoms of pellagra.[5] A single symptom or combinations of symptoms may appear. Skin symptoms include lesions often occurring on skin exposed to sun or at pressure points. The mucous membrane symptoms usually affect the mouth and include glossitis, stomatitis, mouth pain and ulcers, and swelling of the tongue. The vagina and urethra may also be affected. Gastrointestinal symptoms can include burning of the esophagus, abdominal discomfort, constipation, nausea, vomiting, and diarrhea which can be bloody because of ulceration in the bowel. Central nervous system symptoms include psychosis, impaired consciousness, cognitive decline, and dementia. Various symptoms of psychosis can occur including impaired memory, disorientation, confusion, excitement, mania, delirium, or paranoia. In the advanced stages of pellagra mental problems become severe, and death eventually results.

Deficiency of vitamin B6 is associated with conditions such as alcoholism, cirrhosis, hyperthyroidism, malabsorption syndromes and heart failure.[7] Deficiency may also be seen in individuals receiving certain drugs such as isoniazid, hydralazine, or penicillamine. Vitamin B6 deficiency is characterized by seizures, seborrheic dermatitis, glossitis, dizziness, depression, confusion and urinary excretion of xanthurenic acid (a metabolite of tryptophan which may be measured to aid in diagnosing vitamin B6 deficiency).[7,8]

Vitamin B12 deficiency is caused by pernicious anemia, due to insufficient intrinsic factor), or dietary deficiency which may occur in malabsorption states.[10] Deficiency results in megaloblastic anemia and gastrointestinal and neurologic damage with symptoms including weakness, paresthesias, gait abnormalities and cognitive and behavioral changes. Vitamin B12 supplementation reverses anemia and gastrointestinal damage as well as the progression of nerve damage, which may not be completely reversible.

Folic acid deficiency usually results from an overall poor diet, or in conditions associated with broad dietary inadequacies such as chronic alcoholism and malabsorption syndromes.[11] Without a prescription, folic acid supplements are generally restricted to doses of 400 mcg or less since higher doses may mask cobalamin deficiency. High doses of folic acid are not associated with toxicity and reports of adverse effects are rare.

Deficiencies in B vitamins often occur in combination or as a group.[2] Several of the B vitamins are dependent on each other for interconversion and metabolism. For example, vitamin B6 is dependent on riboflavin, niacin, and folic acid.7 Supplementing with a combination B complex vitamin may be useful, especially in subpopulations who are at risk of developing B vitamin deficiency including chronic disease and HIV-AIDS patients, anorexia, chronic alcoholism, and gastrointestinal disorders that increase motility and decrease gastrointestinal passage time, such as diarrhea, infectious enteritis, and excessive consumption of alcohol.[12]

Wernicke-Korsakoff Syndrome is a common neuro-psychiatric complication of chronic alcoholism associated with B vitamin deficiencies and characterized by a wide range of symptoms ranging from physical problems such as motor weakness and ataxia to neurological problems such as memory loss.[1] Alzheimer's disease is also associated with vitamin B deficiency, especially thiamine.[1]

Drug Interactions/Contraindications:

The anticonvulsant drug phenobarbital may induce microsomal oxidation of flavins, and may contribute to deficiency of riboflavin.[2] Chlorpromazine and phenothiazine drugs, as well as certain antibiotics may increase excretion of riboflavin.[2]

In doses of 500 mg and higher niacin (and probably niacinamide) can rarely cause liver toxicity and individuals with liver disease should not take high doses of niacin.[3] Individuals taking niacin at doses of 500 mg and higher are advised to have their physician check levels of uric acid, blood glucose, and liver enzymes before the start of therapy and every six to eight weeks until the dose of niacin is stabilized, and then periodically after.[4]

A number of drugs, including theophylline, cycloserine, hydralazine, phenelzine, gentamicin, penicillamine, isoniazid, L-dopa, and alcohol antagonize vitamin B6 status by binding to a portion of the molecule, inhibiting the metabolism or competing for binding sites.[8] Vitamin B6 may be increased in patients taking estrogens, including oral contraceptives. In most cases pyridoxine supplementation can overcome the deficiencies of vitamin B6 that occur with these drugs.

A number of drugs can interact with vitamin B12, either by antagonizing the hematopoietic response to cobalamin (chloramphenicol), or by impairing the absorption of vitamin B12 (colchicine, aminoglycosides, phenytoin, phenobarbital, primidone and other anticonvulsants, extended-release potassium products, colestipol, cholestyramine, neomycin, para-aminosalicylic acid, zidovudine, and excessive alcohol intake).[10] Metformin may also contribute to food-cobalamin malabsorption especially in elderly patients over long periods of time. Antacids and histamine2-receptor (H2) antagonists such as cimetidine, famotidine, nizatidine, ranitidine and proton pump inhibitors such as esomeprazole, lansoprazole, omeprazole, pantoprazole, and rabeprazole may potentially cause vitamin B12 deficiency by decreasing gastric acid cleavage of vitamin B12 from food sources. Folic acid supplementation may mask vitamin B12 deficiency and thus any anemia should be properly diagnosed before vitamin supplementation begins.

Folic acid should only be used as an adjunct to treatment with vitamin B12 when pernicious anemia is present or suspected.[11] When folic acid is used in pernicious anemia without the addition of vitamin B12 hematologic improvement may occur, while neurologic symptoms continue.

Folic acid therapy in folate-deficient individuals may decrease phenytoin levels.[12] Drugs that may cause deficiency of folate include barbiturates, ethanol, isoniazid, methotrexate, oral contraceptives, phenytoin, primidone, pyrimethamine, sulfasalazine, triamterene and trimethoprim. There may be a reduction or delay in absorption of folic acid when cholestyramine and folic acid are given concurrently. Folic acid is not effective in overdose of folic acid antagonists such as methotrexate.

Biotin, pantothenic acid, choline and inositol have not been reported to interact with any drugs or have any contraindications.[13-17]

Toxicity/Adverse Reactions:

In physiological doses adverse reactions from the B vitamins are minor, and may include gastrointestinal upset such as nausea.[2,4,6,8,10,12,13,15] These effects can be minimized by taking the B vitamins with or after food. Toxicity from the water soluble B vitamins is unlikely to occur except in very high doses since any excess not used by the body is usually readily excreted.[2] Hypersensitivity reactions have been reported with administration of some of the B vitamins, including vitamin B1, vitamin B12, and folic acid.[2,10,12]

No adverse effects have been reported in administration of normal physiologic doses of vitamin B1.[2] Repeated administration of high intravenous doses has rarely been reported to result in pruritis, urticaria, edema, and other effects, including death.

Vitamin B2 is well tolerated and not associated with any toxic effects in normal physiologic doses.[3] In high doses diarrhea and gastrointestinal upset have been reported. Vitamin B2 may cause bright yellow discoloration of the urine due to its fluorescent yellow color.

In doses of 500 mg and higher niacinamide may cause flare up of gout, alter blood glucose levels, and rarely cause liver toxicity.[5,6]

Vitamin B6 is relatively nontoxic in usual doses.[7] Nausea, headache, paresthesia, somnolence and low serum folic acid concentrations have been reported with administration of high doses of vitamin B6.[7,8] Chronic administration of high doses (2 grams or more daily for several months) has been reported to cause sensory neuropathy with symptoms such as ataxia and numbness of hands and feet, with symptoms lessening upon discontinuation of vitamin B6.

As with other B vitamins, vitamin B12 is generally nontoxic even with large doses.[10] Adverse effects have been reported rarely and include mild diarrhea, itch, urticaria, peripheral vascular thrombosis, heart failure exacerbation, and pulmonary edema.

Folic acid is relatively nontoxic, even in large doses.[12] High doses have been rarely reported to cause gastrointestinal symptoms, including anorexia, nausea, abdominal distention, flatulence and bitter taste and central nervous system effects such as difficulty concentrating, irritability, excitement, depression, and confusion.

No adverse effects or toxicity has been reported with even high doses of biotin (daily doses up to 200 mg orally and 20 g intravenously).[13]

No adverse effects have been reported with usual doses of pantothenic acid.[15] High doses of pantothenic acid (15 grams per day) have rarely been reported to cause nausea, gastrointestinal distress, and symptoms of lupus erythematosus.[14]

No adverse effects or toxicity have been reported with choline and inositol supplementation.[16, 17]

Allergen Content/Ingredient Sensitivity:

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

ACCEPTABLE FOR THE FOLLOWING DIETARY RESTRICTION:

Free of animal products

NOT ACCEPTABLE FOR THE FOLLOWING DIETARY RESTRICTION:

Kosher

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