

MULTIVITAMINS + MINERALS

FORTICAP
Film-Coated Tablet
Vitamins / Minerals



PRODUCT DESCRIPTION:
Dark red to maroon, film-coated tablet, capsule-shaped, biconvex, plain on both sides.

FORMULATION:	
Each Film-coated tablet contains:	
Vitamin A Plain	10,000 IU
Vitamin D3	400 IU
Vitamin B1 Mono	10 mg
Vitamin B2	10 mg
Vitamin B6 HCl	10 mg
Vitamin B12	10 mcg
Magnesium Sulfate	4 mg
Vitamin C Coated	150 mg
Vitamin E	100 mg
Ferrous Fumarate	15 mg
Niacin	40 mg
Calcium Gluconate	80 mg
Manganese Sulfate	4 mg
L-Lysine Mono HCl	30 mg
Zinc Sulfate	700 mcg

PHARMACODYNAMICS:
Retinol Acetate (Vitamin A)
Vitamin A is effective for the treatment of Vitamin A deficiency. Vitamin A refers to a group of fat-soluble substances that are structurally related to and possess the biological activity of the parent substance of the group called all-trans retinol or retinol. Vitamin A plays vital roles in vision, epithelial differentiation, growth, reproduction, pattern formation during embryogenesis, bone development, hematopoiesis and brain development. It is also important for the maintenance of the proper functioning of the immune system.

Cholecalciferol (Vitamin D3)
The in vivo synthesis of the predominant two biologically active metabolites of vitamin D occurs in two steps. The first hydroxylation of vitamin D3 cholecalciferol (or D2) occurs in the liver to yield 25-hydroxyvitamin D while the second hydroxylation happens in the kidneys to give 1, 25-dihydroxyvitamin D. These vitamin D metabolites subsequently facilitate the active absorption of calcium and phosphorus in the small intestine, serving to increase serum calcium and phosphate levels sufficiently to allow bone mineralization. Conversely, these vitamin D metabolites also assist in mobilizing calcium and phosphate from bone and likely increase the reabsorption of calcium and perhaps also of phosphate via the renal tubules. There exists a period of 10 to 24 hours between the administration of cholecalciferol and the initiation of its action in the body due to the necessity of synthesis of the active vitamin D metabolites in the liver and kidneys. It is parathyroid hormone that is responsible for the regulation of such metabolism at the level of the kidneys.

Thiamine Mononitrate (Vitamin B1)
Thiamine plays an essential role as a cofactor in the key reactions in carbohydrate metabolism. It acts in two types of reactions upon conversion into the coenzyme thiamine pyrophosphate (TPP): oxidative decarboxylation and transketolation. These reactions are vital in carbohydrate metabolism, specifically in the citric acid cycle (Krebs cycle) and the pentose pathway. Thiamine assists in blood formation and nerve transmission. It is also involved in the conversion of the amino acid tryptophan to the vitamin niacin and the metabolism of the branched-chain amino acids leucine, isoleucine and valine.

Riboflavin (Vitamin B2)
Riboflavin or vitamin B₂ plays an essential role in maintaining human health. Like the other B vitamins, it supports energy production by aiding in the metabolism of fats, carbohydrates and proteins. Vitamin B₂ is also required for red blood cell formation and respiration, antibody production and for regulating human growth and reproduction. Riboflavin (7,8-dimethyl-10-ribityl-isalloxazine) is a water-soluble vitamin present in a wide variety of foods. It was initially isolated; it can be crystallized as orange-yellow crystals and in its pure form is poorly soluble in water. Its most important biologically active forms, Flavin adenine dinucleotide (FAD) and Flavin mononucleotide (FMN), participate in a range of redox reactions, some of which are absolutely key to the function of aerobic cells. Free riboflavin is transported in the plasma bound both to albumin and to certain immunoglobulins, which will also bind Flavin coenzymes. Other riboflavin binding proteins are specific to pregnancy. Riboflavin binding proteins expressed in fetuses of different species are evidently essential to normal fetal development.

Pyridoxine Hydrochloride (Vitamin B6)
Pyridoxine is converted to its active forms, pyridoxal phosphate (PLP) and pyridoxamine phosphate (PMP). PLP facilitates more than 100 different enzymatic reactions that support protein metabolism, blood synthesis, carbohydrate metabolism, and neurotransmitter synthesis. It helps produce a number of neurotransmitters including serotonin, gamma amino butyric acid (GABA), dopamine, and epinephrine. Pyridoxine supports the synthesis of white blood cells of the immune system and is crucial for the synthesis of the hemoglobin rings of red blood cells, which carry oxygen to hemoglobin. Inadequate vitamin B₆ disturbs the binding of oxygen to hemoglobin, causing microcytic hypochromic anemia. In this type of anemia, red blood cells are smaller than normal and also lack sufficient hemoglobin to carry oxygen.

Cyanocobalamin (Vitamin B12)
Cyanocobalamin plays a key role in folate metabolism by transferring a methyl group from the folate coenzyme tetrahydrofolic acid (THFA), which is important in many metabolic pathways. Cyanocobalamin is required in the synthesis of myelin, the white sheath of lipoprotein that surrounds many nerve fibers. During cyanocobalamin deficiency, progressive demyelination of nerve fibers occurs, leading to a variety of neurological symptoms. Cyanocobalamin is involved in biochemical processes essential for DNA synthesis. A cellular deficiency of vitamin B₁₂ can impair DNA synthesis for growth and division of cells. The lack of DNA 12 affects red blood cells which rapidly turn over every 120 days. When red blood cell precursors in the bone marrow are not able to form new DNA, they cannot divide normally to become red blood cells. As these precursor cells continue to synthesize protein and other cell components, they grow into large, fragile, immature cells which displace red blood cells and cause megaloblastic anemia.

Magnesium Sulfate
Magnesium sulfate is a small colorless crystal used as an anticonvulsant, a cathartic, and an electrolyte replenisher in the treatment of pre-eclampsia and eclampsia. It causes direct inhibition of action potentials in myometrial muscle cells. Excitation and contraction are uncoupled, which decreases the frequency and force of contractions. Magnesium sulfate is gaining popularity as an initial treatment in the management of various dysrhythmias, particularly torsade de pointes, and dysrhythmias secondary to TCA overdose or digitalis toxicity.

Ascorbic Acid
Ascorbic Acid (vitamin C) is a water-soluble vitamin indicated for the prevention and treatment of scurvy, as ascorbic acid deficiency results in scurvy. Collagenous structures are primarily affected, and lesions develop in bones and blood vessels. Administration of ascorbic acid completely reverses the symptoms of ascorbic acid deficiency.

Vitamin E
Vitamin E is a collective term used to describe separate fat soluble antioxidants, most commonly alpha-tocopherol. Vitamin E acts to protect cells against the effects of free radicals, which are potentially damaging by-products of the body's metabolism. Vitamin E deficiency is seen in persons with abetalipoproteinemia, premature, very low birth weight infants (birth weights less than 1500 grams, or 3½ pounds), cystic fibrosis, and cholestasis and severe liver disease. Preliminary research suggests vitamin E may help prevent or delay coronary heart disease and protect against the damaging effects of free radicals, which may contribute to the development of chronic diseases such as cancer. It also protects other fat-soluble vitamins (A and B group vitamins) from destruction by oxygen. Low levels of vitamin E have been linked to increased incidence of breast and colon cancer.

Ferrous Fumarate
The major activity of supplemental iron is in the prevention and treatment of iron deficiency anemia. Iron has putative immune-enhancing, anti-carcinogenic and cognition-enhancing activities.

Niacin
Niacin is a B vitamin used to treat vitamin deficiencies as well as hyperlipidemia, dyslipidemia, hypertriglyceridemia, and to reduce the risk of myocardial infarctions. Niacin acts to decrease levels of very low density lipoproteins and low density lipoproteins, while increasing levels of high density lipoproteins. Niacin has a wide therapeutic window with usual oral doses between 500mg and 2000mg. Patients with diabetes, renal failure, uncontrolled hypothyroidism, and elderly patients taking niacin with simvastatin or lovastatin are at increased risk of myopathy and rhabdomyolysis.

Calcium Gluconate
Calcium Gluconate is the gluconate salt of calcium. An element or mineral necessary for normal nerve, muscle, and cardiac function, calcium as the gluconate salt helps to maintain calcium balance and prevent bone loss when taken orally. This agent may also be chemo-preventive for colon and other cancers.

Manganese Sulfate
Manganese is a constituent of enzyme systems including those involved in lipid synthesis, the tricarboxylic acid cycle and purine and pyrimidine metabolism. It is bound to arginase of the liver and activates many enzymes.

L-Lysine Hydrochloride
Insures the adequate absorption of calcium; helps form collagen (which makes up bone cartilage & connective tissues); aids in the production of antibodies, hormones & enzymes. Recent studies have shown that Lysine may be effective against herpes by improving the balance of nutrients that reduce viral growth. A deficiency may result in tiredness, inability to concentrate, irritability, bloodshot eyes, retarded growth, hair loss, anemia & reproductive problems.

Zinc Sulfate
Zinc has been identified as a cofactor for over 70 different enzymes, including alkaline phosphatase, lactic dehydrogenase and both RNA and DNA polymerase. Zinc facilitates wound healing, helps maintain normal growth rates, normal skin hydration and the senses of taste and smell.

PHARMACOKINETICS:
Retinol Acetate (Vitamin A)
Except when liver function is impaired, Vitamin A is readily absorbed. β-carotene (as in Forceval Capsules) is Pro-Vitamin A and is the biological precursor to Vitamin A. It is converted to Vitamin A (Retinol) in the liver; retinol is emulsified by bile salts and phospholipids and absorbed in a micellar form. Part is conjugated with glucuronic acid in the kidney and part is metabolized in the liver and kidney, leaving 30 to 50% of the dose for storage in the liver. It is bound to a globulin in the blood. Metabolites of Vitamin A are excreted in the feces and the urine.

Cholecalciferol (Vitamin D3)
The metabolism of ergocalciferol is similar to that of cholecalciferol. Cholecalciferol is absorbed from the gastro-intestinal tract into the circulation. In the liver, it is hydroxylated to 25-hydroxycholecalciferol, is subject to entero-hepatic circulation and is further hydroxylated to 1,25-dihydroxycholecalciferol in the renal tubule cells. Vitamin D metabolites are bound to specific plasma proteins.

Thiamine Mononitrate (Vitamin B1)
Thiamine is readily absorbed in the jejunum by active transport and passive diffusion mechanisms. It is transported by the portal and systemic circulations to the liver and to the various tissues in the body. Thiamine is metabolized in the liver and excreted in the urine.

Riboflavin (Vitamin B2)
Most riboflavin is absorbed in the proximal small intestine. The body absorbs little riboflavin from single doses beyond 27 mg and stores only small amounts of riboflavin in the liver, heart, and kidneys. When excess amounts are consumed, they are either not absorbed or the small amount that is absorbed is excreted in urine.

Pyridoxine Hydrochloride (Vitamin B6)
Pyridoxine is readily absorbed from the jejunum after oral administration. It is stored mainly in the liver and lesser amount, in the muscle and brain. Pyridoxine is converted to the active forms pyridoxal phosphate and pyridoxamine phosphate. In the liver, pyridoxal is oxidized to 4-pyridoxic acid which is excreted in the urine.

Cyanocobalamin (Vitamin B12)
Cyanocobalamin is absorbed from the gastro-intestinal tract and is extensively bound to specific plasma proteins. A study with labelled Vitamin B12 showed it was quickly taken up by the intestinal mucosa and held there for 2-3 hours. Peak concentrations in the blood and tissues did not occur until 8-12 hours after dosage with maximum concentrations in the liver within 24 hours. Cobalamins are stored in the liver, excreted in the bile and undergo enterohepatic recycling. Part of a dose is excreted in the urine, most of it in the first eight hours.

Magnesium Sulfate
Magnesium Sulfate is slowly and poorly absorbed from the gastrointestinal tract (approx one-third is absorbed from the small intestine). Distributed to bones and extracellular fluids. Crosses the placenta, enters breastmilk. Plasma protein-binding: 30% to albumin. Magnesium is excreted solely by the kidney at a rate proportional to the serum concentration and glomerular filtration.

Ascorbic Acid
Ascorbic acid is readily absorbed from the gastro-intestinal tract and is widely distributed in the body tissues. Ascorbic acid in excess of the body's needs is rapidly eliminated in the urine and this elimination is usually accompanied by a mild diuresis.

Vitamin E
Vitamin E is absorbed from the gastro-intestinal tract. Most appears in the lymph and is then widely distributed to all tissues. Most of a dose is slowly excreted in the bile and the remainder is eliminated in the urine as glucuronides of tocopheronic acid or other metabolites.

Ferrous Fumarate
Iron is absorbed chiefly in the duodenum and jejunum. Absorption is aided by the acid secretion of the stomach and if the iron is in the ferrous state as in ferrous fumarate. In conditions of iron deficiency, absorption is increased and, conversely, it is decreased in iron overload. Iron is stored as ferritin.

Niacin
Absorbed from the stomach and small intestine. Absorption is facilitated by sodium-dependent diffusion, and at higher intakes, via passive diffusion.

Calcium Gluconate
A third of ingested calcium is absorbed from the small intestine. Absorption of calcium decreases with age.

Manganese Sulfate
Manganese salts are poorly absorbed.

L-Lysine Hydrochloride
Absorbed from the lumen of the small intestine into the enterocytes by an active transport process.

Zinc Sulfate
Zinc is poorly absorbed from the gastro-intestinal tract. It is widely distributed throughout the body. It is excreted in the feces with traces appearing in the urine.

INDICATIONS:
Supplement daily or for the therapy of vitamins and minerals deficiency. It is also used for conditions like malnutrition, convalescence, post surgery, geriatric, acute and chronic infections, febrile diseases, severe wound burns and toxic conditions. Highly recommended for pregnancy and lactation, anemias and for patients with restricted diet.

DOSAGE AND ADMINISTRATION:
One to two tablets daily or as prescribed by the physician.

CONTRAINDICATION:
Hypercalcemia, haemochromatosis and other iron storage disorders. Hypersensitivity to the active substance(s) or to any of the excipients.

SPECIAL PRECAUTIONS:
Upon taking the Forticap film-coated tablet, protein and energy are also required to provide complete nutrition in the daily diet. No other vitamins, minerals or supplements with or without vitamin A should be taken with this preparation except under medical supervision. Do not take on an empty stomach. If symptoms persist, consult your doctor.

PREGNANCY AND LACTATION:
Can be taken during pregnancy and lactation at the recommendation of the physician.

DRUG INTERACTIONS:
The effect of levodopa may be reduced when vitamin B is administered concomitantly. Pyridoxine-Antagonists Ex. Isoniazid, Cycloserine, Penicillamine, Hydralazine. The efficacy of vitamin B₆ (pyridoxine) may be decreased. Loop Diuretics ex. Furosemide: In long-term use, the blood level of thiamine may be reduced.

ADVERSE EFFECTS:
The vitamins contained in Vitamin B-Complex are completely non-toxic even in high doses and usually, no side effects occur. Sensitivity to Vitamin B however, may sometimes be encountered if administration is at prolonged intervals,

Liver dysfunctions could also predispose patients to hypersensitivity reactions. Nevertheless, it must be stressed that hypersensitivity to Vitamin B is very rare when orally given unlike if administered by intravenous injection where hypersensitivity is more often encountered.

OVERDOSE AND TREATMENT:
Prolonged overdose of Vitamin B₁, for longer than 2 months and >1 g daily, may lead to neurotoxic effects. If iron overdose is suspected, symptoms may include nausea, vomiting, diarrhea, abdominal pain, hematemesis, rectal bleeding, lethargy and circulatory collapse. Hyperglycemia and metabolic acidosis may also occur. Treatment should be implemented immediately. In severe cases, after a latent phase, relapse may occur after 24 - 48 hours, manifest by hypotension, coma and hepatocellular necrosis and renal failure.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C. Protect from light.

AVAILABILITY:
Aluminum Foil Strip x 4's (Box of 100's)

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

Keep out of reach of children.

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.

REGISTRATION NUMBER:
DRP-3842-01

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