

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

I - VIT™ PLUS

(EPA, DHA, Methylcobalamin, Folic acid, Coenzyme Q 10 with Minerals and Vitamins Capsule)

COMPOSITION

Each soft gelatin capsule contains:

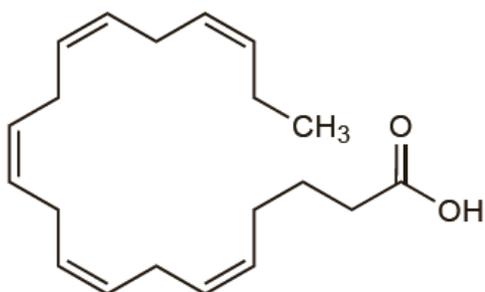
Eicosapentaenoic acid (EPA)	120 mg
Docosahexaenoic acid (DHA)	90 mg
Methylcobalamin	750 mcg
Vitamin B ₆ IP	3 mg
Folic acid IP	1.5 mg
Co-enzyme Q10 USP	30 mg
Chromium (As chromium picolinate)	80 mcg
Copper (as copper sulphate BP)	2 mg
Zinc (as Zinc sulphate Monohydrate IP)	40 mg
Lycopene USP	5000 mcg
Excipients	q.s.

Approved colour used in capsule shell.

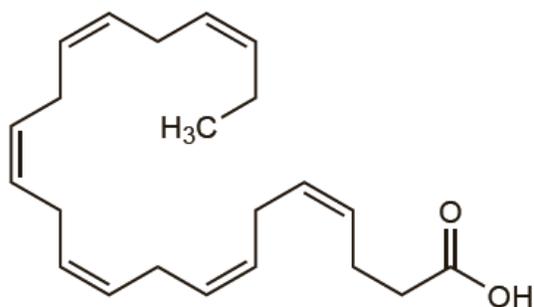
DESCRIPTION

Eicosapentaenoic acid (EPA) and Docosahexaenoic acid (DHA):

Eicosapentaenoic acid chemically it is (all-Z)-Eicosapenta-5,8,11,14,17-enoic acid. It is having chemical formula of C₂₀H₃₀O₂ and molecular weight of 302.5.

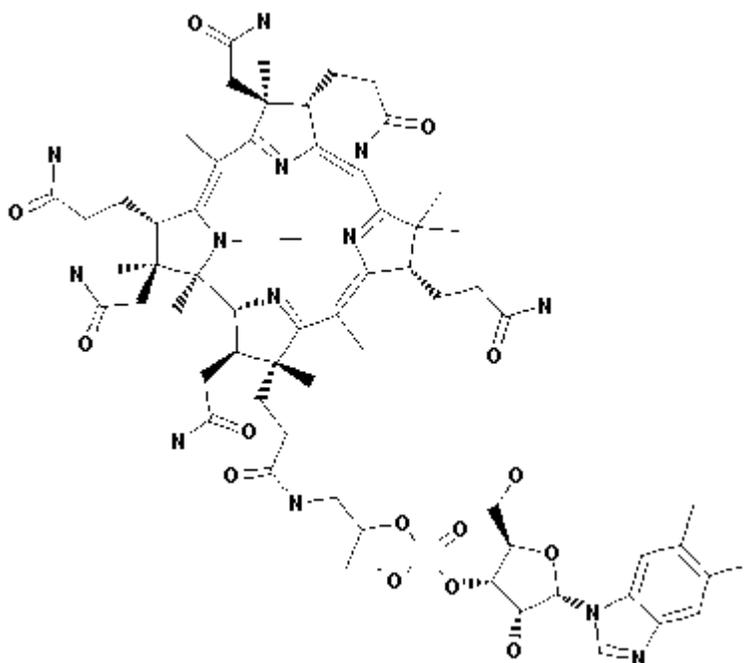


Docosahexaenoic acid chemically it is (all-Z)-Docosahexa-4,7,10,13,16,19-enoic acid. It is having a molecular formula of C₂₂H₃₂O₂ and molecular weight of 328.5.



Methylcobalamin:

Methylcobalamin or mecobalamin is having molecular weight of 1344.38gram/mol with molecular formula of $C_{63}H_{91}CoN_{13}O_{14}$. It is having a structural formula as follows:



Vitamin B₆

Pyridoxine helps in synthesis and degradation of biogenic amines. It helps to control carbohydrate and fat metabolism.

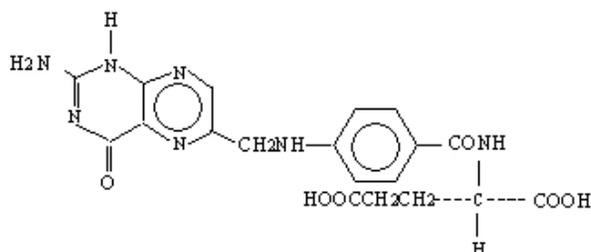
Pyridoxine Hydrochloride RDA. 2mg.

Folic acid

Folic acid, N-[p-[[[(2-amino-4-hydroxy-6-pteridiny) methyl]-amino]benzoyl]-L-glutamic acid, is a B complex vitamin containing a pteridine moiety linked by a methylene bridge to para-aminobenzoic acid, which is joined by a peptide linkage to glutamic acid. Conjugates of folic acid are present in a wide variety of foods, particularly liver, kidneys, yeast, and leafy green vegetables. Commercially available folic acid is prepared synthetically. Folic acid occurs as a yellow or yellowish-orange crystalline powder and is very slightly soluble in water and insoluble in alcohol. Folic acid is readily soluble in dilute solutions of alkali hydroxides and carbonates and solutions of the drug may be prepared with the aid of sodium hydroxide or sodium carbonate, thereby forming the

soluble sodium salt of folic acid (sodium folate). Aqueous solutions of folic acid are heat sensitive and rapidly decompose in the presence of light and/or riboflavin; solutions should be stored in a cool place protected from light.

The structural formula of folic acid is as follows:



$C_{19}H_{19}N_7O_6$ M.W. 441.40

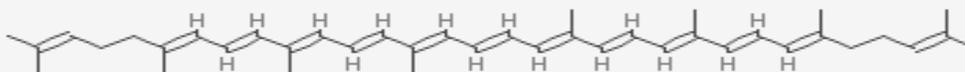
Co-enzyme Q10

Chemically it is 10. 2- Deca (3-methylbut-2-enylene)-5, 6 – dimethoxy - 3-methyl – p – benzoquinone. Molecular formula is $C_{59}H_{90}O_4$ and empirical formula 863.3.



Lycopene

Lycopene, a carotenoid without provitamin-A activity. It is a red, fat-soluble pigment found in certain plants and microorganisms, where it serves as an accessory light-gathering pigment and protects these organisms against the toxic effects of oxygen and light. It is having molecular formula of $C_{40}H_{56}$ and molecular weight of 536.87.



Chromium

Chromium is an element. Its molecular weight is 51.99.

Copper

Copper is an element. Its molecular weight is 63.546.

Zinc

Zinc is an element. Its molecular weight is 65.38.

CLINICAL PHARMACOLOGY

Eicosapentaenoic acid and Docosahexaenoic acid:

Omega-3 fatty acids are long-chain polyunsaturated fatty acids containing 18 to 22 carbon atoms and a varying number of double bonds, the first of which is in the n-3 position. They have an important role as eicosanoid precursors and as components of cell membranes; in humans, they compete with arachidonic acid, an omega-6 fatty acid

precursor. Their actions in humans include a hypolipidaemic action (especially a reduction in plasma triglycerides), an anti-inflammatory action, and an antiplatelet effect.

Pyridoxine

Natural substances that have vitamin B6 activity are pyridoxine in plants and pyridoxal or pyridoxamine in animals. All 3 are converted to pyridoxal phosphate by the enzyme pyridoxal kinase. The physiologically active forms of vitamin B6 are pyridoxal phosphate (codecarboxylase) and pyridoxamine phosphate. Riboflavin is required for the conversion of pyridoxine phosphate to pyridoxal phosphate.

Vitamin B6 acts as a coenzyme in the metabolism of protein, carbohydrate, and fat. In protein metabolism, it participates in the decarboxylation of amino acids, conversion of tryptophan to niacin or to serotonin (5-hydroxytryptamine), deamination, and transamination and transulfuration of amino acids. In carbohydrate metabolism, it is responsible for the breakdown of glycogen to glucose-1-phosphate.

The total adult body pool consists of 16 to 25 mg of pyridoxine. Its half-life appears to be 15 to 20 days. Vitamin B6 is degraded to 4-pyridoxic acid in the liver. This metabolite is excreted in the urine.

Pyridoxine readily absorbed from the gastrointestinal tract after oral dose and 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.

Methylcobalamin

Methylcobalamin is one of the biologically active form of vitamin B12. It acts as coenzymes in nucleic acid synthesis. Methylcobalamin is also closely involved with folic acid in several important metabolic pathways. Methylcobalamin supports the methionine synthetase reaction, which is essential for normal metabolism of folate.

It binds to intrinsic factor; a glycoprotein secreted by the gastric mucosa, and is then actively absorbed from the gastrointestinal tract. Absorption is impaired in patients with an absence 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.

It is extensively bound to specific plasma proteins called transcobalamins; transcobalamin II appears to be involved in the rapid transport of the cobalamins to tissues. A parent form -vitamin B12 is stored in the liver, excreted in the bile, and undergoes extensive enterohepatic recycling; part of a dose is excreted in the urine, most of it in the first 8 hours; urinary excretion, however, accounts for only a small fraction in the reduction of total body stores acquired by dietary means. Vitamin B12 diffuses across the placenta and also appears in breast milk.

Coenzyme Q10

Coenzyme Q10 (CoQ10) is the Co-enzyme essential for production of ATP in mitochondria of all cells including sperm cells. It helps in electron and proton transfer across mitochondrial layers. CoQ10 is found in almost every cell in the body, and it is a powerful antioxidant.

Ubidecarenone is a naturally occurring coenzyme involved in electron transport in the mitochondria. It is claimed to be a free radical scavenger and to have antioxidant and membrane stabilizing properties. It has been given by mouth as an adjunct in cardiovascular disorders, including mild or moderate heart failure. It has also been tried in other conditions associated with coenzyme deficiency, and is promoted as a dietary supplement.

Folic acid

Folic acid acts on megaloblastic bone marrow to produce a normo-blastic marrow. In man, an exogenous source folate is required for nucleo-protein synthesis and the maintenance of normal erythropoiesis. Folic acid is the precursor of tetrahydrofolic acid, which is involved as a cofactor for transformylation reactions in the biosynthesis of purines and thymidylates of nucleic acids. Impairment of thymidylate synthesis in patients with folic acid deficiency is thought to account for the defective deoxyribonucleic acid (DNA) synthesis that leads to megaloblast formation and megaloblastic and macrocytic anemias.

Chromium

Chromium is an essential trace element that potentiates insulin action and thus influences carbohydrate, lipid, and protein metabolism.

Copper

Copper is an essential trace element although severe copper deficiency, which is associated with anaemia, neutropenia, and bone demineralisation, is rare in humans.

Zinc

It is a constituent of many enzyme systems and is present in all tissues.

Absorption of zinc from the gastrointestinal tract is incomplete, and is reduced in the presence of some dietary constituents such as phytates. Bioavailability of dietary zinc varies widely between different sources, but is about 20 to 30%. Zinc is distributed throughout the body with the highest concentrations found in muscle, bone, skin, eye, and prostatic fluids. It is primarily excreted in the faeces, and regulation of faecal losses is important in zinc homeostasis. Small amounts are lost in urine and perspiration.

Lycopene

It is having an antioxidant property. Lycopene has the capacity to prevent free radical damage to cells caused by reactive oxygen species. It is a potent antioxidant *in vitro* and in human studies, reducing the susceptibility of lymphocyte DNA to oxidative damage, inactivating hydrogen peroxide and nitrogen dioxide, and protecting lymphocytes from nitrogen oxide-induced membrane damage and cell death twice as efficiently as beta-carotene.

INDICATIONS

Useful as a co-prescription in the management of chronic diseases like

Cardiovascular disorders such as hyperlipidemia, prehypertension/hypertension, coronary artery disease;

Diabetes associated conditions such as insulin resistance, prediabetes, polycystic ovary syndrome, multiple sclerosis;

Chronic inflammatory condition such as rheumatoid arthritis;

Ophthalmological conditions such as cataract, glaucoma, diabetic retinopathy, age related macular degeneration.

Infertility.

CONTRAINDICATION

Hypersensitivity to any of the components of formulation.

Folic acid is contraindicated in patients who have shown previous intolerance to the drug. Long term folate therapy is contraindicated in any patients with in treated cobalamin deficiency. This can be untreated pernicious anaemia or other cause of cobalamin deficiency, including lifelong vegetarians. No harm results from short course of folate.

WARNINGS AND PRECAUTIONS

Pyridoxine

Single deficiency, as of pyridoxine alone, is rare. Multiple vitamin deficiency is to be expected in any inadequate diet. Patients treated with levodopa should avoid supplemental vitamins that contain more than 5 mg pyridoxine in the daily dose. Women taking oral contraceptives may exhibit increased pyridoxine requirements.

Methylcobalamin

Should be given with caution in patients suffering from folate deficiency.

The following warnings and precautions suggested with parent form – vitamin B12

The treatment of vitamin B12 deficiency can unmask the symptoms of polycythemia vera.

Megaloblastic anemia is sometimes corrected by treatment with vitamin B12. But this can have very serious side effects. Don't attempt vitamin B12 therapy without close supervision by your healthcare provider.

Do not take vitamin B12 if Leber's disease, a hereditary eye disease. It can seriously harm the optic nerve, which might lead to blindness.

Folic acid

Administration of folic acid alone is improper therapy for pernicious anemia and other megaloblastic anemias in which vitamin B12 is deficient.

Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurologic manifestations remain progressive.

There is a potential danger in administering folic acid to patients with undiagnosed anemia, since folic acid may obscure the diagnosis of pernicious anemia by alleviating the hematologic manifestations of the disease while allowing the neurologic complications to progress. This may result in severe nervous system damage before the correct diagnosis is made. Adequate doses of vitamin B12 may prevent, halt, or improve the neurologic changes caused by pernicious anemia.

Coenzyme Q-10

Caution is advised if you have diabetes, alcohol dependence, liver disease, phenylketonuria (PKU), or any other condition that requires you to limit/avoid these substances in your diet. Ask your doctor or pharmacist about using this product safely.

High blood pressure or low blood pressure: Coenzyme Q-10 might lower blood pressure. It can increase the effects of medications used to lower blood pressure.

Surgery: Coenzyme Q-10 might interfere with blood pressure control during and after surgery. Stop using coenzyme Q-10 at least two weeks before a scheduled surgery.

No data are available for zinc, copper, chromium, lycopene, and selenium.

DRUG INTERACTION

Pyridoxine

Pyridoxine supplements should not be given to patients receiving levodopa, because the action of the latter drug is antagonized by pyridoxine. However, this vitamin may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa.

Pyridoxine reduces the activity of altretamine.

It has also been reported to decrease serum concentrations of phenobarbital and phenytoin.

Methylcobalamin

The data are unavailable for methylcobalamin drug interaction, however evidences for parent drug – vitamin B12 are as follows

Absorption from the gastrointestinal tract may be reduced by neomycin, aminosalicylic acid, histamine H₂-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 B₁₂ in anaemia.

Potassium supplements can reduce absorption of vitamin B12 in some people and might contribute to vitamin B12 deficiency.

Folic acid, particularly in large doses, can cover up vitamin B12 deficiency, and cause serious health effects.

Early research suggests that vitamin C supplements can destroy dietary vitamin B12. It isn't known whether this interaction is important, but to stay on the safe side, take vitamin C supplements at least 2 hours after meals.

Heavy drinking for at least a two-week period can decrease vitamin B12 absorption from the gastrointestinal tract.

Folic acid

There is evidence that the anticonvulsant action of phenytoin is antagonized by folic acid. A patient whose epilepsy is completely controlled by phenytoin may require increased doses to prevent convulsions if folic acid is given.

Folate deficiency may result from increased loss of folate, as in renal dialysis and/or interference with metabolism (e.g. folic acid antagonists such as methotrexate); the administration of anticonvulsants, such as diphenylhydantoin, primidone, and barbiturates; alcohol consumption and, especially alcoholic cirrhosis; and the administration of pyrimethamine and nitrofurantoin.

False low serum and red cell folate levels may occur if the patient has been taking antibiotics, such as tetracycline, which suppress the growth of *Lactobacillus casei*.

Coenzyme Q-10

Moderate

Be cautious with this combination.

Medications for cancer (Chemotherapy)

Coenzyme Q-10 is an antioxidant. There is some concern that antioxidants might decrease the effectiveness of some medications used for cancers. But it is too soon to know if the interaction occurs.

Medications for high blood pressure (Antihypertensive drugs)

Coenzyme Q-10 seems to decrease blood pressure. Taking coenzyme Q-10 along with medications for high blood pressure might cause your blood pressure to go too low.

Some medications for high blood pressure include captopril (Capoten), enalapril (Vasotec), losartan (Cozaar), valsartan (Diovan), diltiazem (Cardizem), Amlodipine (Norvasc), hydrochlorothiazide (HydroDIURIL), furosemide (Lasix), and many others.

Warfarin (Coumadin)

Warfarin (Coumadin) is used to slow blood clotting while coenzyme Q-10 might increase blood clotting. By helping the blood clot, coenzyme Q-10 might decrease the effectiveness of warfarin (Coumadin) and increase the risk of dangerous clots. Be sure to have your blood checked regularly. The dose of your warfarin (Coumadin) might need to be changed.

Red yeast

Red yeast might reduce coenzyme Q-10 levels.

Chromium

Data are not available.

Copper

Large doses of zinc supplements may inhibit the gastrointestinal absorption of copper.

Zinc

The absorption of zinc may be reduced by iron supplements, penicillamine, phosphorus-containing preparations, and tetracyclines. Zinc supplements reduce the absorption of copper, fluoroquinolones, iron, penicillamine, and tetracyclines.

Lycopene

Cholesterol-lowering drugs (e.g., probucol), mineral oil, fat substitutes, and pectin may decrease the absorption of lycopene; whereas, beta-carotene, medium-chain triglycerides, and dietary oils such as olive oil may enhance the absorption of lycopene.

ADVERSE EFFECTS

Eicosapentaenoic acid and Docosahexaenoic acid

The most common adverse effects of omega-3 fatty acid preparations are gastrointestinal disturbances, particularly at high doses, including nausea, eructation, vomiting, abdominal distension, diarrhoea, and constipation. There have been rare reports of acne and eczema. Moderate increases in hepatic transaminases have been reported in patients with hypertriglyceridaemia. There is a theoretical possibility of vitamin E deficiency with long-term use.

Omega-3 fatty acids have antithrombotic activity and should be given with caution to patients with haemorrhagic disorders or to those receiving anticoagulants or other drugs affecting coagulation. Hepatic function should be monitored in patients with hepatic impairment, particularly if receiving high doses. Caution may also be required in asthmatic patients sensitive to aspirin since omega-3 fatty acids may affect prostaglandin synthesis.

Pyridoxine

Paresthesia, somnolence, and low serum folic acid levels have been reported.

Symptoms of dependence have been noted in adults given only 200 mg daily, followed by withdrawal.

Long-term use of large doses of pyridoxine is associated with the development of severe peripheral neuropathies (including severe sensory neuropathy); the dose at which these occur is controversial.

Methylcobalamin

Pulmonary edema and congestive heart failure early in treatment; peripheral vascular thrombosis.

Polycythemia vera may also reported.

Mild transient diarrhea has also reported.

Rarely itching; transitory exanthema.

Other adverse effects reported with vitamin B12 are diarrhea, blood clots, itching, serious allergic reactions.

Folic acid

Allergic sensitization has been reported following both oral and parenteral administration of folic acid.

Folic acid is relatively nontoxic in man. Rare instances of allergic responses to folic acid preparations have been reported and have included erythema, skin rash, itching, general malaise, and respiratory difficulty due to bronchospasm.

One patient experienced symptoms suggesting anaphylaxis following injection of the drug. Gastrointestinal side effects, including anorexia, nausea, abdominal distention, flatulence, and a bitter or bad taste, have been reported in patients receiving 15 mg folic acid daily for 1 month. Other side effects reported in patients receiving 15 mg daily include altered sleep patterns, difficulty in concentrating, irritability, overactivity, excitement, mental depression, confusion, and impaired judgment. Decreased vitamin B12 serum levels may occur in patients receiving prolonged folic acid therapy.

In an uncontrolled study, orally administered folic acid was reported to increase the incidence of seizures in some epileptic patients receiving phenobarbital, primidone, or diphenylhydantoin. Another investigator reported decreased diphenylhydantoin serum levels in folate-deficient patients receiving diphenylhydantoin who were treated with 5 mg or 15 mg of folic acid daily.

Co-enzyme Q10

Co-enzyme Q10 is well tolerated. Mild side effects include stomach upset, loss of appetite, nausea, vomiting, and diarrhea. It can cause allergic skin rashes in some people. It also might lower blood pressure.

Chromium

There have been rare reports of cutaneous reactions to oral chromium tripicolinate, including of acute generalised exanthematous pustulosis.

Copper

Adverse effects from copper have tended to arise after absorption of the metal from cooking utensils and during dialysis. Ingestion of copper from cooking utensils is associated mainly with hepatotoxicity. Dialysis procedures may supply copper through the water supply or from parts of the equipment and when this happens patients may suffer haemolysis and other haematological reactions, kidney involvement, and hepatotoxicity; the toxicity is generally a result of poor equipment maintenance. Adverse effects attributed to copper have been reported in women with copper-containing intra-uterine devices. There have been isolated case reports of various effects such as allergy

and endometrial changes. However, it is difficult to separate those adverse effects that are due to the device from those due solely to the copper.

The symptoms of Wilson's disease (hepatolenticular degeneration) are due to an accumulation of copper in various parts of the body.

Copper salts if ingested can produce severe gastrointestinal effects and there may be systemic absorption of copper leading to the effects discussed above. The use of sprays of copper salts in agriculture has been associated with lung changes. Treatment of copper poisoning is symptomatic and may involve the use of a chelating agent to remove any absorbed metal. Dialysis has been tried.

Cirrhosis and acute liver failure have been attributed to chronic excessive copper supplement ingestion.

Supplementation with 10 mg daily of copper (around the safe upper limit) for 2 months has been reported to be associated with transient mild increases in serum aminotransferase values.

Zinc

The most frequent adverse effects of zinc salts (the gluconate and sulfate) given orally are gastrointestinal and include abdominal pain, dyspepsia, nausea, vomiting, diarrhoea, gastric irritation, and gastritis. These are particularly common if zinc salts are taken on an empty stomach, and may be reduced by giving them with meals.

Isolated cases reported of anaemia, leucopenia, and neutropenia in patients consuming excessive amounts of zinc supplements.

Hypersensitivity reactions, like palmoplantar pustulosis also reported.

Lycopene

Lycopene is generally considered safe, non-toxic, and consumption is usually without side effects.

OVERDOSAGE

Pyridoxine

Pyridoxine given to animals in amounts of 3 to 4 g/kg of body weight produces convulsions and death. In man, a dose of 25 mg/kg of body weight is well tolerated.

Methylcobalamin

Evidences are un-available for overdose of methylcobalamine.

Chromium

Cases of renal failure were attributed to ingestion of excessive doses of chromium tripicolinate in women with no history of renal dysfunction. Acute renal failure with features of acute tubular necrosis, and requiring haemodialysis, has been reported after ingestion of a chromium picolinate- containing supplement. The amount of chromium in the supplement could not be determined.

Zinc

In acute overdose zinc salts are corrosive, due to the formation of zinc chloride by stomach acid; treatment consists of giving milk or alkali carbonates and activated charcoal. The use of emetics or gastric lavage should be avoided.

Prolonged use of high doses of zinc supplements, orally or parenterally, leads to copper deficiency with associated sideroblastic anaemia and neutropenia; full blood counts and serum cholesterol should be monitored to detect early signs of copper deficiency. Zinc toxicity has occurred after the use of contaminated water in haemodialysis solutions.

High serum zinc concentrations may be reduced by using a chelating drug such as sodium calcium edetate.

Limited data are available with copper, lycopene, Co-enzyme Q-10, eicosapentaenoic acid and docosahexaenoic acid.

DOSAGES AND ADMINISTRATION

As per physician's discretion.

USE IN PREGNANCY, NURSING MOTHER, USE IN CHILDREN AND OLDER PATIENTS

Pyridoxine

Pregnancy Category A-The requirement for pyridoxine appears to be increased during pregnancy. Pyridoxine is sometimes of value in the treatment of nausea and vomiting of pregnancy.

The need for pyridoxine is increased during lactation. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when pyridoxine hydrochloride is administered to a nursing woman.

Methylcobalamin

Vitamin B₁₂ is likely safe for pregnant or breast-feeding women when taken by mouth in the amounts recommended. Don't take larger amounts. The safety of larger amounts is unknown.

No data available for use of methylcobalamin in special population.

Folic acid

Teratogenic Effects

Pregnancy Category A

Folic acid is usually indicated in the treatment of megaloblastic anemias of pregnancy. Folic acid requirements are markedly increased during pregnancy, and deficiency will result in fetal damage.

Studies in pregnant women have not shown that folic acid increases the risk of fetal abnormalities if administered during pregnancy. If the drug is used during pregnancy, the possibility of fetal harm appears remote. Because studies cannot rule out the possibility of harm, however, folic acid should be used during pregnancy only if clearly needed.

Folic acid is excreted in the milk of lactating mothers. During lactation, folic acid requirements are markedly increased; however, amounts present in human milk are adequate to fulfill infant requirements, although supplementation may be needed in low birth-weight infants, in those who are breast-fed by mothers with folic acid deficiency (50 µg daily), or in those with infections or prolonged diarrhea.

Zinc

Zinc requirements are increased in pregnancy.

Lycopene

Scientific evidence for lycopene use in pregnancy is not available; however, no adverse events have been reported in association with the consumption of lycopene-containing foods during pregnancy. Obtaining lycopene from food sources, rather than supplements, during pregnancy and while nursing has been suggested.

Limited data are available for the chromium, copper, and selenium.

Coenzyme Q-10

Not enough is known about the use of coenzyme Q-10 during pregnancy and breast-feeding. Stay on the safe side and avoid use.

Use coenzyme Q10 chewable tablets with caution in children.

Limited data are available for the chromium, copper, and selenium.

EXPIRY DATE

It should not be used later than expiry.

STORAGE

Store in a cool and dry place. Protect from direct sun light. Keep out of reach of children.

PRESENTATION

10x10 Capsules.

MANUFACTURED BY

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MARKETED BY



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