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

I Vit Tablets
(Dietary supplement)

COMPOSITION

Each serving (film coated tablet) contains

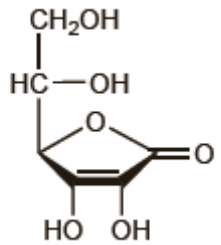
Astaxanthin	2mg
Vitamin C	75mg
Vitamin E (As dl-Alpha tocopheryl acetate)	25mg
Zinc (Elemental) as Zinc oxide	40mg
Vitamin A (As acetate)	10mg
Copper (Elemental) as cupric oxide	2mg
Chromium (As chromium picolinate)	2mg
Selenium (Elemental as sodium selenate)	40mcg

Ingredients: Dibasic calcium phosphate, lacotse, astaxanthin, microcrystalline cellulose, vitamin C, vitamin E acetate, zinc oxide, poluvinylpyrrolidone, starch, croscarmellose sodium, colloidal silicon dioxide, crospovidone, instacoal universal A05D00491 (red colour 171, 124, 122, 110), talc, hydroxypropylmethylcelluose, vitamin A acetate, magnesium stearate, colour 171, cupric oxide, polyethylene glycol, Instaglow IG-003, chromium picolinate, sodium selenate, butylated hydroxyanisole, butylated hydroxytoluene, propyl gallate.

DESCRIPTION

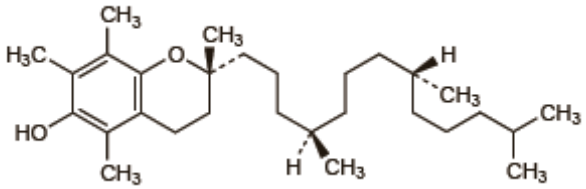
Vitamin C

It is having a molecular weight of 176.1 and empirical formula of $C_6H_8O_6$. The structure is as follows:



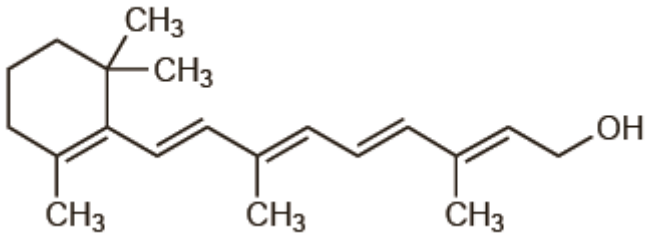
Vitamin E (As dl-Alpha tocopheryl acetate)

It is having a molecular weight of 472.7 and empirical formula of $C_{31}H_{52}O_3$. The structure is as follows:



Vitamin A

Vitamin A is 15-Apo-β-caroten-15-ol; 3,7-Dimethyl-9-(2,6,6-trimethylcyclohex-1-enyl)nona-2,4,6,8-tetraen-1-ol. It is having a molecular weight of 286.5 and empirical formula of $C_{20}H_{30}O$. The structure is as follows:



Astaxanthin

Astaxanthin belongs to the carotenoid family and powerful antioxidant. Astaxanthin can span through cell membrane and mitochondrial membrane and quench free radicals in both hydrophilic and hydrophobic areas.

Chromium

Chromium is an element. Its molecular weight is 51.99.

Selenium

It is an element. Its molecular weight is 78.96.

Copper

Copper is an element. Its molecular weight is 63.546.

Zinc

Zinc is an element. Its molecular weight is 65.38.

CLINICAL PHARMACOLOGY

Vitamin C

Vitamin C, a water-soluble vitamin, is essential for the synthesis of collagen and intercellular material.

Ascorbic acid is readily absorbed from the gastrointestinal tract and is widely distributed in the body tissues. Ascorbic acid in excess of the body's needs is rapidly eliminated in the urine.

The most established function of vitamin C in the body is the control of the formation of colloidal intercellular substances. Deficiency of vitamin C leads to scurvy and in the

absence of this water-soluble vitamin, a typical nutritional anaemia develops; the vitamin acts directly on the blood-forming centres and is essential for the maturation of the red blood cells.

Vitamin E

The exact role of vitamin E in the animal organism has not yet been established. Vitamin E is known to exert an important physiological function as an antioxidant for fats, with a sparing action on vitamin A, carotenoids and on unsaturated fatty acids. Other work has demonstrated that vitamin E is connected with the maintenance of certain factors essential for the normal metabolic cycle.

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

Vitamin A

Vitamin A, a fat-soluble vitamin, is essential for growth, for the development and maintenance of epithelial tissue, and for vision, particularly in dim light.

Vitamin A substances are readily absorbed from the gastrointestinal tract but absorption may be reduced in the presence of fat malabsorption, low protein intake, or impaired liver or pancreatic function. Vitamin A esters are hydrolysed by pancreatic enzymes to retinol, which is then absorbed and re-esterified. Some retinol is stored in the liver. It is released from the liver bound to a specific α1-globulin (retinol-binding protein) in the blood. The retinol not stored in the liver undergoes glucuronide conjugation and subsequent oxidation to retinal and retinoic acid; these and other metabolites are excreted in urine and faeces. Vitamin A does not readily diffuse across the placenta (but see Pregnancy, above), but is present in breast milk.

Astaxanthin

Astaxanthin belongs to the carotenoid family and powerful antioxidant. Astaxanthin can span through cell membrane and mitochondrial membrane and quench free radicals in both hydrophilic and hydrophobic areas.

Chromium

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

Selenium

Selenium is an essential trace element. It is an integral part of the enzyme system glutathione peroxidase, which protects intracellular structures against oxidative damage.

Selenium compounds are generally readily absorbed from the gastrointestinal tract. Selenium is stored in red blood cells, the liver, spleen, heart, and nails. It is converted in tissues to its metabolically active forms. Selenium is excreted in the urine, and to a lesser extent in the faeces.

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 homoeostasis. Small amounts are lost in urine and perspiration.

INDICATIONS
It is used for dietary supplement as an antioxidant.

CONTRAINDICATION
Hypersensitivity to any of the components of formulation.
As this product contains lactose, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
In the condition of hyperoxaluria.

WARNINGS AND PRECAUTIONS
Vitamin C
Increased intake of ascorbic acid over a prolonged period may result in an increase in renal clearance and deficiency may result if it is withdrawn too rapidly.

Vitamin E
Vitamin E has been reported to increase the risk of thrombosis in patients predisposed to this condition, including patients taking oestrogens. This finding has not been confirmed but should be borne in mind when selecting patients for treatment, in particular women taking oral contraceptives containing oestrogens.
A higher incidence of necrotising enterocolitis has been noted in lower weight premature infants (less than 1.5kg) treated with vitamin E.

Vitamin A
Gastrointestinal absorption of vitamin A may be impaired in cholestatic jaundice and fat-malabsorption conditions.

Astaxanthin
There are no data available for use in children, pregnant and lactating woman for astaxanthin thus it is not recommended to use in thispopulations.

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

DRUG INTERACTION

Vitamin C

Concomitant administration of aluminium-containing antacids may increase urinary aluminium elimination. Concurrent administration of antacids and ascorbic acid is not recommended, especially in patients with renal insufficiency.

Concomitant administration of aspirin and ascorbic acid may interfere with absorption of ascorbic acid. Renal excretion of salicylate is not affected and does not lead to reduced anti-inflammatory effects of aspirin.

Concurrent administration of ascorbic acid with desferrioxamine enhances urinary iron excretion. Cases of cardiomyopathy and congestive heart failure have been reported in patients with idiopathic haemochromatosis and thalassaemias receiving desferrioxamine who were subsequently given ascorbic acid. Ascorbic acid should be used with caution in these patients and cardiac function monitored.

Ascorbic acid may interfere with biochemical determinations of creatinine, uric acid and glucose in samples of blood and urine.

Vitamin E

Vitamin E may increase the risk of thrombosis in patients taking oestrogens.

Vitamin A

Absorption of vitamin A from the gastrointestinal tract may be reduced by the presence of neomycin, colestyramine, or liquid paraffin.

There is an increased risk of hypervitaminosis A if vitamin A is given with synthetic retinoids such as acitretin, isotretinoin, and tretinoin.

There is conflicting evidence regarding the effect of vitamin A on the response to measles vaccine.

Astaxanthin

Data are not available.

Chromium

Data are not available.

Selenium

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.

ADVERSE EFECTS

Vitamin C

Nausea, vomiting and stomach cramps.
Flushing or redness of skin, headache, mild increase in urination with doses greater than 600mg per day.
Large doses of ascorbic acid (greater than 1g per day) may cause diarrhea.

Vitamin E
Diarrhoea and abdominal pain may occur with doses greater than 1g daily.

Vitamin A
The use of excessive amounts of vitamin A substances over long periods can lead to toxicity. Rarely, acute toxicity may also occur with very high doses.
Hypervitaminosis A (chronic toxicity) is characterized by fatigue, irritability, anorexia and loss of weight, vomiting and other gastrointestinal disturbances, low-grade fever, hepatomegaly, skin changes (yellowing, dryness, sensitivity to sunlight), pruritus, alopecia, dry hair, cracking and bleeding lips, anaemia, headache, hypercalcaemia, subcutaneous swelling, nocturia, and pains in bones and joints.
Symptoms of chronic toxicity may also include raised intracranial pressure and papilloedema mimicking brain tumours, and visual disturbances which may be severe. Symptoms usually clear on withdrawal of vitamin A, but in children premature closure of the epiphyses of the long bones may result in arrested bone growth.
Acute vitamin A intoxication is characterised by sedation, dizziness, confusion, diarrhoea and vomiting, sore mouth, bleeding gums, desquamation, and increased intracranial pressure (resulting in bulging fontanelle in infants or severe headache in adults).
Hepatomegaly and visual disturbances may occur; irritability may be severe.
Hypervitaminosis A does not appear to be a problem with large doses of carotenoids.
Enhanced susceptibility to the effects of vitamin A may be seen in children and in patients with liver disease.
Excessive doses of vitamin A should be avoided in pregnancy because of potential teratogenic effects; for further details see Pregnancy, below.
High doses of vitamin A cause increased intracranial pressure, and, in infants, this is manifested as bulging of the fontanelle.
Excessive dietary intake of vitamin A may be associated with osteoporosis.
Vitamin A is stored in the Dissë space of liver cells and excessive dosage can lead to fibrosis and obstruction of sinusoidal blood flow, causing non-cirrhotic portal hypertension and hepatocellular dysfunction.
Normochromic macrocytic anaemia developed in a patient who had been receiving vitamin A 150 000 units daily by mouth for several months.

Astaxanthin
Reports of urticarial, skin rashes, abdominal pain, abdominal distention, change in stool color (red color) have been reported.

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

Selenium
Limited data are available.

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.

OVERDOSAGE
Vitamin C
Ascorbic acid may cause acidosis or haemolytic anaemia in certain individuals with a deficiency of glucose 6-phosphate dyhydrogenase. Renal failure can occur with massive ascorbic acid overdosage.
Gastric lavage may be given if ingestion is recent otherwise general supportive measures should be employed as required.

Vitamin E
Transient gastro-intestinal disturbances have been reported with doses greater than 1g daily and where necessary, general supportive measures should be employed.

Vitamin A

Although no clinical manifestations of toxicity were seen in 3 boys who ingested large amounts of vitamin A, their serum retinol concentrations continued to rise over about 3 weeks, and took several months to normalise; the authors cautioned that the use of chewable vitamins resembling confectionery may increase the risk of overdose in children.

Astaxanthin

Limited data are available. Intake of generally dose up to 30mg daily is well tolerated.

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.

Selenium

Overdosage of selenium has been associated with loss of hair, nail changes, diarrhoea, dermatitis, metallic taste, garlic odour of breath, irritability, fatigue, and peripheral neuropathy.

Chronic exposure to high amounts of selenium has been reported to cause toxic effects on endocrine function, hepatotoxicity, gastrointestinal disturbances, and dermatological effects such as nail and hair loss and dermatitis. There has been some suggestion also of neurotoxicity, and a possible increased risk of amyotrophic lateral sclerosis. Studies have had conflicting results, and different inorganic and organic forms may vary greatly in biological activity, toxicity, and nutritional importance.

Acute toxicity has also been reported; characteristic symptoms of selenium toxicity are garlicky or sour breath odour, vomiting and gastrointestinal disturbances, restlessness, hypersalivation, muscle spasms, haemolysis, liver necrosis, cerebral and pulmonary oedema, coma, and death. A man who had taken vitamin tablets containing between 500 and 1000 times the amount of selenium labelled on the bottle developed generalised alopecia, changes in nail colour, diarrhoea, worsening fatigue, and paraesthesias. Two weeks after stopping the vitamins, early regrowth of hair and yellowish-white and red transverse lines on his nails were noted. In another case, an elderly man who was concerned that he might have prostate cancer ingested 10 g of sodium selenite. He developed significant abdominal pain, vomiting and diarrhoea, hypotension, and ventricular tachycardia. Blood tests showed acidosis, hypokalaemia and an excessive selenium concentration. Despite symptomatic therapy, he suffered a cardiac arrest and died.

Zinc

In acute overdosage 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.

DOSAGES AND ADMINISTRATION
One or two tablets as per physician's discretion.

USE IN PREGNANCY, NURSING MOTHER, USE IN CHILDREN AND OLDER PATIENTS
Vitamin C
Ascorbic acid in doses greater than 1g should not be administered during pregnancy as the effect of large doses on the foetus is not known.
No problems are anticipated with the administration of ascorbic acid tablets during lactation.

Vitamin E
There is no evidence of the safety of high doses of vitamin E in pregnancy nor is there evidence from animal work that it is free from hazard, therefore do not use in pregnancy especially in the first trimester. No information is available on excretion in breast milk, therefore it is advisable not to use during lactation.

Vitamin A
A prospective cohort study found that a total daily intake of vitamin A from all sources of greater than 15 000 units during early pregnancy was associated with a significantly increased risk of birth defects of structures arising from the cranial neural crest.
The American College of Obstetricians and Gynecologists has recommended that women who are pregnant or planning pregnancy should ensure that any vitamin supplements they take contain a daily dose of vitamin A of no more than 5000 units.

Astaxanthin
Astaxanthin is not studied in the pregnant woman, lactating mothers, children hence it is not recommended to use in this specific population.

Zinc
Zinc requirements are increased in pregnancy.

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

EXPIRY DATE
It should not be used later than expiry.

STORAGE
Store in a dry place below 30 degree Celsius temperature.

PRESENTATION
1x15 tablets.

MANUFACTURED BY
Maxcure Nutravedics Limited.
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Sidcul, Haridwar-249403.

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