UNILAB

MULTIVITAMINS + MINERALS

VIGOR -ACE ®

SOFTGEL CAPSULE

FORMULATION

Each softgel capsule contains:

Retinol Palmitate (Vitamin A).....7,500 IU
dl-Alpha Tocopheryl Acetate (Vitamin E).....100 IU
Ascorbic Acid (Vitamin C).....250 mg
Selenium (from Selenium Yeast) ..... 50 mcg
Zinc (as Sulfate) .....20 mg
Lecithin, Soya.....200 mg

PRODUCT DESCRIPTION

This product is a maroon, oblong, soft gelatin capsule, 16 minims in size with white "VIGOR-ACE" imprint.

WHAT IS IN THE MEDICINE?

This nutritional supplement contains antioxidant nutrients such as vitamins A, C, E, zinc, and selenium which together help the body's natural defense against free radicals. Free radicals are highly reactive and unstable chemicals affecting various cells in the body including the skin. It also contains lecithin, an essential component of cell membranes.

NUTRIENTS	ANTIOXIDANT AND OTHER FUNCTIONS
Vitamin A	● A fat-soluble antioxidant which stabilizes and protects against free radicals in the lipid (fat) phase of cells ● Stimulates the production of T-lymphocytes, important immune cells which protect the body against harmful bacteria, parasites and viruses ● Helps maintain the normal health and function of the skin which provides the first line of defense against invading microorganisms ● Helps maintain normal vision ● Deficiency of vitamin A results in hyperkeratosis (thickening of palms, soles, elbows, knees, wrists, and ankles), impaired immune function, and night blindness
Vitamin C	● The major water-soluble antioxidant which acts as first defense against free radicals in the aqueous (water) phase including blood, plasma and other intracellular and extracellular fluids ● Cofactor of enzymes involved in the formation of collagen, the most abundant protein essential in the formation of bones, teeth, cartilage, and skin. Collagen provides elasticity to the skin and helps promote faster wound healing ● Forms part of the body's natural immune system; stimulates the activity of antibodies and immune cells which inhibit foreign antigens harmful to the body ● Deficiency of vitamin C results in delayed wound healing, impaired immune function and scurvy manifested as weakness, shortness of breath, muscle cramps, dry, rough and feverish skin covered with reddish-blue spots, and bleeding gums
Vitamin E	● The major fat-soluble antioxidant which stabilizes and protects against free radicals in the lipid (fat) phase of cells ● Helps maintain healthy skin by inhibiting the formation of lipofuscin, a brown pigment that accumulates in tissues during aging ● Deficiency in vitamin E results in various neurological disorders, skin damage, hemolytic anemia (breakdown of red blood cells), retinopathy (defective eye function), and abnormalities in function of platelets and lymphocytes
Zinc	● Essential for skin integrity, wound healing and acts as cofactor of various enzymes involved in cell division and growth ● A cofactor of the enzyme superoxide dismutase which is involved in the removal of harmful free radicals ● Required for the normal development and maintenance of the immune system; helps regulate the activity of cells involved in immune function ● Deficiency in zinc results in dermatitis of extremities or limbs, delayed skeletal maturation, impaired immune infection, diarrhea, and growth retardation
Selenium	● Supports the antioxidant activity of vitamin E by forming part of the enzyme glutathione peroxidase which converts free radicals to harmless substances Helps maintain the integrity of the muscle and red blood cells, and of keratin, the tough protein of hair and nails ● Deficiency in selenium results in impaired immune function
Lecithin	● A source of choline which is a precursor of acetylcholine, an important neurotransmitter ● Essential for cell membrane integrity and repair ● Facilitates the movement of fats in and out of cells needed for proper liver function

STRENGTH OF THE MEDICINE

Please see ***Formulation.***

WHAT IS THE MEDICINE USED FOR?

For the prevention and treatment of vitamin and/or mineral deficiencies

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Recommended Adult Dose: Orally, one softgel capsule daily.
Or, as directed by a doctor.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

- If you are allergic to any ingredient in the product
- If you are pregnant or breastfeeding
- Vitamin A is contraindicated in patients who have hypervitaminosis A.

UNDESIRABLE EFFECTS

The amount of nutrients in this product is relatively nontoxic and is usually well tolerated. However, undesirable effects may occur, particularly when the nutrients are used at high doses (e.g., concomitant use of other multivitamin-mineral supplements), see also ***Signs and Symptoms of Overdosage.***

Vitamin A: Dermatitis and photosensitivity reactions may occur.

Vitamin C: Vitamin C at a dose of 1 g or more daily may cause diarrhea. Other gastrointestinal (GI) disturbances associated with high vitamin C intake include nausea, vomiting, abdominal cramps, heartburn, esophagitis (rare), transient colic, and flatulent distension. Fatigue, flushing, headache, insomnia, sleepiness, and mild increase in urination have also been reported.

Ascorbic acid may cause acidification of the urine, precipitation of urate, cystine, or oxalate stones, or drugs in the urinary tract. However, reports of kidney stone formation associated with large dosages of ascorbic acid reportedly have been limited to individuals with preexisting renal disease, and data from epidemiologic studies do not support an association between excess ascorbic acid intake and kidney stone formation in apparently healthy individuals.

Patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency reportedly have developed hemolysis after large oral doses of ascorbic acid. Rarely, decreased blood pH leading to sickle-cell crisis has been reported in patients with sickle-cell disease.

Vitamin E: Vitamin E (e.g., at dosages exceeding 300 IU daily) has rarely caused nausea, diarrhea, abdominal pain/intestinal cramps, fatigue/weakness, headache, dizziness, blurred vision, emotional disturbances, and rash. Myopathy (muscle disorder), hypertension, thrombophlebitis (vein inflammation related to a blood clot), gonadal dysfunction, breast soreness/gynecomastia, creatinuria (increased concentration of creatine in the urine), increased serum creatine kinase, serum cholesterol, and triglycerides; increased urinary estrogens and androgens; and thyroid problems have also been noted. These effects generally disappeared after discontinuing the vitamin.

Doses of vitamin E greater than 1,000 mg (equivalent to 1,490 IU) daily for prolonged periods have occasionally been associated with increased bleeding tendency in vitamin K-deficient patients such as those taking oral anticoagulants. It has also been suggested that it may increase the risk of thrombosis in some patients, such as those taking estrogens.

Selenium: Excessive selenium exposure may cause abdominal pain and cramps, diarrhea, nausea, vomiting, garlic-like breath odor, hair and nail changes, fatigue, and irritability.

Zinc: Doses of zinc up to 30 mg/day are generally well tolerated. Higher doses may cause gastrointestinal (GI) side effects such as nausea, vomiting, abdominal pain/cramps, dyspepsia, GI discomfort/irritation, gastritis, and diarrhea. Other adverse reactions reported include metallic taste, loss of appetite, headache, and drowsiness.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

The following interactions have been noted particularly when the nutrients are used at high doses:

Vitamin A

- **Anticoagulant (e.g., warfarin):** Concomitant administration with large doses of vitamin A may lead to increased risk of bleeding.
- **Retinoid (e.g., etretinate, isotretinoin, tretinoin):** Avoid concomitant use of retinoids and preparations containing vitamin A or its derivatives because of the potential for additive undesirable effects.
- **Minocycline:** Concomitant administration may lead to increased risk of pseudomotor cerebri.
- **Statins:** Prolonged statin treatment may increase serum vitamin A levels.

Vitamin C

- **Paracetamol:** Ascorbic acid increases the apparent half-life of paracetamol.

Vitamin E

- **Anticoagulants:** Vitamin E reportedly may have anti-vitamin K effects; concomitant intake of anticoagulants (e.g., warfarin) and vitamin E may result in hemorrhage (bleeding).
- **Antiplatelets:** High doses of vitamin E may also potentiate the effects of antiplatelets (e.g., aspirin, clopidogrel, ticlopidine) and herbs with antithrombotic activity such as garlic and ginkgo.

Zinc

- **Antibiotics (cephalosporins, quinolones, tetracyclines):** Zinc decreases the absorption of these antibiotics. Taking the antibiotic at least 2 hours before or 4 to 6 hours after taking zinc supplement minimizes this interaction.
- **Bisphosphonates** (alendronate, etidronate, risedronate)**:** Concomitant intake of a bisphosphonate and zinc may decrease the absorption of both the bisphosphonate and zinc.
- **Cholesterol medicines:** Additive effects are possible with concomitant administration; use with caution.
- **Copper or iron:** Concomitant administration with zinc inhibits the absorption of copper and iron. Administer zinc and copper or iron as far apart as possible.

Tell your doctor about other medicines you are taking including supplements and herbal products.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you miss a dose, just take the next dose and the subsequent doses at the usual recommended schedule, i.e., once a day. Do not double the dose.

HOW SHOULD YOU KEEP THIS MEDICINE?

- Keep the product out of reach and sight of children.
- Store at temperatures not exceeding 30°C.
- Protect from heat, light and moisture.

SIGNS AND SYMPTOMS OF OVERDOSAGE

Vitamin A

Chronic daily vitamin A intakes in excess of 10,000 IU or weekly intakes in excess of 25,000 IU have resulted in hypervitaminosis A. Early signs of hypervitaminosis A include fatigue, lethargy (lack of energy), irritability, malaise/depression, loss of appetite, abdominal pain/discomfort, nausea and vomiting, mild fever, and excessive sweating. Treatment of hypervitaminosis A consists of discontinuance of vitamin A and supportive therapy as indicated.

Other symptoms of vitamin A toxicity include blurred or double vision, dizziness, drowsiness, headache, insomnia, lack of muscle coordination, seizures, papilledema, raised intracranial pressure; bulging fontanelle (in infants), hypercalcemia (due to increase in activity of alkaline phosphatase), bone and joint pain, rapid resorption of bone/hyperostosis, osteoporosis, osteosclerosis, skin disorders (dermatitis, dryness, pruritus/itching, redness, scaliness, skin peeling, rash), cracking of the lips, loss of hair, diarrhea, weight loss, cessation of menstruation in women, and liver damage, which in turn leads to jaundice.

Not all signs appear in all patients, and relative severity varies widely among different individuals. Most signs and symptoms disappear within a week, but skin and bone changes may remain evident for several months.

A long term study also suggests that high intake of vitamin A (≥ 2,000 mcg of retinol per day) is related to increased risk of hip fractures in older women.

Excessive vitamin A intake (more than 10,000 IU daily) is hazardous when taken during the first and second trimesters of pregnancy. Excessive vitamin A intake during pregnancy may lead to birth defects such as cleft palate, heart abnormalities and brain malformations, e.g., hydrocephalus and microcephaly (baby with a very small head).

Vitamin C

Prolonged intake of ascorbic acid (vitamin C) in excess of 2 g per day may lead to nausea, abdominal cramps, diarrhea, and nose bleeds. Elevated serum glucose levels, GI obstruction, and esophagitis have also been reported in those taking high oral doses of vitamin C.

In people with kidney disease, excess vitamin C also may contribute to oxalate-containing kidney stones. In healthy people, epidemiological studies do not support an association between excess vitamin C intake and kidney stones. High vitamin C intake may also boost iron absorption – useful for some, but problematic for people with hemochromatosis, a metabolic disease that cause excess iron accumulation.

Vitamin E

There are no available data on acute overdosage with vitamin E. However, large doses have occasionally been associated with side effects (see ***Undesirable Effects***).

Selenium

Prolonged intakes of selenium (doses of 1,000 mcg or greater daily) may lead to selenosis. Symptoms include fatigue, irritability, garlic-like breath odor, GI upset, nausea, vomiting, hair and nail brittleness and loss; skin rash, tooth decay, mild nerve damage, and hyperreflexia (overresponsive reflexes).

Zinc

Signs of acute zinc toxicity (doses >200 mg daily) include GI pain/cramps, nausea, vomiting, and diarrhea, loss of appetite, headache, lethargy, muscle pains, and fever.

Prolonged zinc supplementation may cause impairment of copper and iron status, and anemia at doses >50 mg/day; immune deficiency, reduced blood high-density lipoprotein (HDL) levels, and gastric erosion at doses >150 mg daily.

Long-term (average 6.3 years) ingestion of supplemental zinc (80 mg/day) has also been linked to a significant increase in hospitalizations for urinary tract infections and kidney stones.

Lecithin

Nausea, diarrhea, and increased salivation have been occasionally reported with the use of lecithin in doses >3.5 g per day.

WHAT TO DO WHEN YOU HAVE USED MORE THAN THE RECOMMENDED DOSAGE?

If you have taken more than the recommended dosage, consult a doctor.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE

- Oral vitamin A preparations should not be used for treating vitamin A deficiency in persons with malabsorption syndromes.
- Chronic consumption of vitamin A may cause liver damage
- Vitamin C should be used with caution in patients with renal failure (risk of oxalate stones), erythrocyte glucose-6-phosphate dehydrogenase (G6PD) deficiency (risk of hemolytic anemia), hemochromatosis, sickle cell anemia (risk of precipitating a crisis), thalassemia, or sideroblastic anemia.
- High doses of vitamin E (i.e., doses greater than 100 IU) should be used with caution in patients on warfarin. Monitoring of international normalized ratio (INR) and adjusting of warfarin dose (if indicated) are recommended. Likewise, those with vitamin K deficiencies, such as patients with liver failure, should be cautious in taking high doses of vitamin E.
- Vitamin E should be used with extreme caution in those with any lesions that have a tendency to bleed (e.g., bleeding peptic ulcers), those with a history of hemorrhagic stroke, and those with inherited bleeding disorders (e.g., hemophilia).
- Zinc should be used with caution in patients with kidney disease.
- Do not use more than the recommended dose. If you are taking other supplements, read the label, since those supplements may contain the same ingredients as this product.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT A DOCTOR?

- Patients under the care of a doctor or those receiving any other medication should consult a physician before taking this product.
- Consult a doctor before using this product if you:
  - have a history of stroke or risk factors for stroke;
  - have any coagulation (blood clotting) problem or you are taking anticoagulants (e.g., warfarin)
- If any undesirable effect occurs.

AVAILABILITY

In HDPE bottles of 30 and 75 softgel capsules.

ADVERSE DRUG REACTION REPORTING STATEMENT

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at +632-8-**UNILAB**-1 (+632-8-**864522**-1) for Metro Manila or toll-free +1-800-10-UNILAB-1 for provinces, or e-mail productsafety@unilab.com.ph.
By reporting undesirable effects, you can help provide more information on the safety of this medicine.

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