Multivitamins Mineral

Each softgel capsule contains:
Retinol Palmitate (Vitamin A).....5000 IU
dl-Alpha Tocopheryl Acetate (Vitamin E).....100 IU
Ascorbic Acid (Vitamin C).....500 mg
Zinc (as Sulfate).....25 mg

Conzace®
Soft Gel Capsule

PRODUCT DESCRIPTION
Multivitamins + Mineral (Conzace®) is a green, oblong, soft gelatin capsule.

WHAT IS IN THE MEDICINE?
This nutritional supplement is formulated with vitamins A, C, E and zinc to help enhance the body's natural immune function and help improve body resistance against illness and infections. These nutrients are also known to help the body's antioxidant defense system against damaging free radicals. Dietary intake may not be enough to meet the daily requirements to protect the body from various diseases. Thus, dietary supplementation is important to consider.

NUTRIENTS	IMMUNE, ANTIOXIDANT AND OTHER FUNCTIONS
Vitamin A	• Stimulates the production of T-lymphocytes, important immune cells which protect the body against harmful bacteria, parasites and viruses. • A fat-soluble antioxidant which stabilizes and protects against free radicals in the lipid (fat) phase of cells. • Helps maintain the normal health and function of the skin which provides the first line of defense against invading microorganisms • Helps maintain normal vision • Vitamin A deficiency results in impaired antibody production and lymphocyte responsiveness, hyperkeratosis (thickening of palms, soles, elbows, knees, wrists, and ankles) and night blindness
Vitamin C	• 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 • 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. • Deficiency of vitamin C results in impaired immune function, delayed wound healing 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	• It modulates the synthesis of prostaglandins important for the body's immune response. • 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. • Vitamin E deficiency leads to impaired antibody production and impaired function of phagocytes, 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	• Required for the normal development and maintenance of the immune system; helps regulate the activity of cells involved in immune function. • A cofactor of the enzyme superoxide dismutase which is involved in the removal of harmful free radicals. • Essential for skin integrity, wound healing and acts as cofactor of various enzymes involved in cell division and growth • Zinc deficiency results in impaired T-cell development, impaired lymphocyte responsiveness, decreased resistance to infections, dermatitis of extremities or limbs, hair loss, delayed skeletal maturation, diarrhea, and growth

STRENGTH OF THE MEDICINE Please see formulation.

WHAT IS THIS MEDICINE USED FOR?
A nutritional supplement, for adults 19 years old and above, for the prevention and treatment of vitamins and/or mineral deficiencies.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?
Orally, one softgel capsule once a day. 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
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*. In general, the amount of nutrients in this product is relatively nontoxic and is usually well tolerated.

Vitamin A

Skin and subcutaneous tissue disorders: Dermatitis, photosensitivity reactions

Vitamin C

Blood and lymphatic system disorders: Hemolysis [after large oral doses of ascorbic acid in patients with glucose-6-phosphate dehydrogenase (G6PD) deficiency]
Immune system disorders: Delayed-type allergic response
Psychiatric disorders: Insomnia, sleepiness
Nervous system disorders: Headache
Vascular disorders: Flushing
Gastrointestinal disorders: Abdominal cramps, diarrhea (at a dose of 1 g or more daily), esophagitis (rare), flatulent distention, gastric discomfort, heartburn, intestinal obstruction (rare), nausea, transient colic, vomiting
Renal and urinary disorders: Increased urination (mild), kidney stone formation (associated with large dosages of ascorbic acid reportedly have been limited to individuals with preexisting renal disease)
Injury, poisoning and procedural complications: Erosion of dental enamel

Vitamin E

Endocrine disorders: Thyroid problems
Nervous system disorders: Dizziness, headache
Eye disorders: Blurred vision
Vascular disorders: Hypertension, thrombophlebitis (vein inflammation related to a blood clot)
Gastrointestinal disorders: Nausea, diarrhea, abdominal pain/intestinal cramps
Skin and subcutaneous tissue disorders: Rash
Musculoskeletal and connective tissue disorders: Myopathy (pain or weakness in the muscles)
Reproductive system and breast disorders: Breast soreness/gynecomastia, gonadal dysfunction
Investigations: Creatinuria (increased concentrations of creatine in the urine), increased serum creatine kinase, serum cholesterol, and triglycerides; increased urinary estrogens and androgens
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.

Zinc

Doses of zinc up to 30 mg/day are generally well tolerated.
Metabolism and nutrition disorders: Loss of appetite
Psychiatric disorders: Drowsiness
Nervous system disorders: Headache, metallic taste
Gastrointestinal disorders: Abdominal pain/cramps, diarrhea, dyspepsia, gastritis, gastrointestinal discomfort/irritation, nausea, vomiting

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

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

• **Antacids:** Increased risk of aluminum toxicity has been noted with concomitant use; therefore, it is not recommended, especially in patients with renal insufficiency.
• **Aspirin:** Concomitant intake may lead to increased urinary excretion of ascorbic acid and decreased excretion of aspirin.
• **Disulfiram:** Prolonged administration of large doses (1 g daily) of vitamin C may interfere with the alcohol-disulfiram reaction.
• **Fluphenazine:** Concomitant administration with ascorbic acid resulted in decreased fluphenazine plasma level.
• **Mexiletine:** Large doses (1 g daily) of ascorbic acid may accelerate excretion of mexiletine.
• **Paracetamol:** Ascorbic acid increases the apparent half-life of paracetamol.
• **Oral contraceptives** (containing estrogens): These may reduce blood levels of ascorbic acid; large doses (> 1 g) of vitamin C may increase plasma estrogen levels (possibly converting low-dose oral contraceptive to high-dose oral contraceptive); possibly breakthrough bleeding associated with withdrawal of high-dose vitamin C.
• **Warfarin:** Ascorbic acid has reportedly decreased the anticoagulant effect of warfarin.
• **Others:** Acidification of the urine following ascorbic acid administration may result in altered excretion of other drugs.

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.

Interference with Laboratory Tests:

Vitamin C interferes with the results of the following laboratory tests: paracetamol, asparte aminotransferase, bilirubin, carbamazepine, creatinine, glucose, lactate dehydrogenase, stool guiaic, theophylline, and uric acid.

Tell your doctor about other medicines you are taking including supplements and herbal products, and other caffeine-containing products.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you miss the dose for the day, just take the next dose and the subsequent doses at the usual recommended schedule, i.e.,once a day.

Do not double the dose unless recommended by a doctor.

HOW SHOULD YOU KEEP THIS MEDICINE?

• Store at temperatures not exceeding 30°C.
• Keep the product out of sight and reach of children.
• 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 vitamin C (ascorbic acid) 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*).

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.

WHAT TO DO WHEN YOU HAVE TAKEN 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 YOUR DOCTOR?

• If any undesirable effect occurs.
• If you are pregnant or breastfeeding, consult a doctor before using this product.

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY: Box of 100's (flex foil strips x 10's)
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