ASCORBIC ACID SODIUM ASCORBATE ZINC

CEELIN® PLUS CHEWABLES

20 mg/90 mg/5 mg Chewable Tablet
Vitamin and Mineral

FORMULATION

Each chewable tablet contains:

Ascorbic acid	20 mg
Sodium ascorbate (equivalent to 80 mg Ascorbic acid)	90 mg
Zinc citrate trihydrate (equivalent to 5 mg elemental Zinc)	16.03 mg

PRODUCT DESCRIPTION

Orange, mottled, round, biconvex, chewable tablet, with PEDIATECH® logo on one side, plain on the other side

WHAT IS IN THE MEDICINE?

Vitamin C and zinc together help the body's natural defense against damaging free radicals (antioxidant effect) and help boost immune function. Free radicals are highly reactive and unstable chemicals generated during normal body activities that require oxygen (e.g., respiration, digestion, blood circulation, immune system response, increased physical activity, etc.) and after exposure to UV light, cigarette smoke and various pollutants. Zinc participates in enzyme systems that influence cell division and proliferation. It also influences hormonal regulation of cell division through its effect on insulin-like growth factor (IGF-1). Hence, zinc is needed for normal growth of children and adolescents, cell renewal and cell repair. Vitamin C and zinc have other important functions:

NUTRIENTS	FUNCTIONS
Vitamin C	• The body's 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 • A 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 strength and elasticity to the skin and helps promote faster wound healing • Forms part of the body's natural immune system; it stimulates the activity of antibodies and immune cells which inhibit foreign antigens such as bacteria and viruses that are harmful to the body
Zinc	• Cofactor of various enzymes involved in cell division and growth • Required for the normal development and maintenance of the immune system; helps regulate the activity of cells involved in immune function • Functions as an antioxidant by being a cofactor of the enzyme superoxide dismutase which is involved in the removal of harmful free radicals • Essential for skin integrity and wound healing; it promotes tissue repair by stimulating cell division through proper connective tissue formation

STRENGTH OF THE MEDICINE

Please see Formulation

WHAT IS THIS MEDICINE USED FOR?

This nutritional supplement is used for the prevention and treatment of deficiencies of vitamin C and zinc.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Age Group	Recommended Dose
	Orally, once a day.
4 – 8 years	1 chewable tablet
9 – 13 years	1 – 2 chewable tablets
	Or, as directed by a doctor. For young children, the tablet should be chewed first before swallowing. For older children, the tablet may be chewed or swallowed whole with water.

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

If you are allergic to any ingredient in the product

UNDESIRABLE EFFECTS

The amount of nutrients in this product is relatively nontoxic and is usually well tolerated.

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

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?

The following interactions should be considered before giving this medicine:

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.

Zinc

- **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.
- **Penicillamine**: Concomitant administration reduces zinc absorption.
- **Quinolones**: Zinc decreases absorption of quinolone antibiotics (e.g., ciprofloxacin, levofloxacin, ofloxacin). Zinc salts or vitamins containing zinc should be given 2 hours after or 6 hours before antibiotics.
- **Tetracycline**: Concomitant administration results in decreased tetracycline effectiveness. Administer tetracycline at least 2 hours before or 3 hours after zinc.
- **Food**: Concomitant intake of caffeine or tea and zinc reduces zinc absorption. Food containing high amounts of phosphorus, calcium (dairy), or phytates (e.g., bran, brown bread) may also reduce its absorption.

Interference with Laboratory Tests:

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

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.
Do not double the dose unless recommended by your doctor.

HOW SHOULD YOU KEEP THIS MEDICINE?

Store at temperatures not exceeding 30°C.
Always keep container tightly closed.
Keep the product out of sight and reach of children.

SIGNS AND SYMPTOMS OF OVERDOSAGE

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, gastrointestinal 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 intakes may also boost iron absorption – useful for some, but problematic for people with hemochromatosis, a metabolic disease that cause excess iron accumulation.
Uric acid excretion may be increased by ascorbic acid; 1 g of the vitamin daily reportedly caused no change in serum uric acid concentrations while 8 g daily resulted in decreased serum uric acid. Theoretically, large doses of ascorbic acid could result in gouty arthritis in susceptible individuals and in the formation of uric acid stones (especially in individuals who normally excrete large amounts of uric acid in urine).

Zinc

Signs of acute zinc toxicity (doses >200 mg/day) include gastrointestinal pain/cramps, nausea, vomiting, diarrhea, loss of appetite, headache, lethargy (sleepiness), muscle pain, 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/day.
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

- Vitamin C should be used with caution in patients with renal failure (risk of oxalate stones); diabetes mellitus (interference with glucose determinations); erythrocyte G6PD deficiency (risk of hemolytic anemia); hemochromatosis; sickle cell anemia (risk of precipitating a crisis); thalassemia; or sideroblastic anemia.
- Tolerance may be induced with prolonged use of large doses (>1 g daily), resulting in symptoms of deficiency when intake is reduced to normal.
- Zinc should be used with caution in patients with kidney disease.
- Do not take more than the recommended dose.
- Do not use after the expiry date on the label.

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

If any undesirable effect occurs.

AVAILABILITY

1 Box of 20mg/90mg/5mg Chewable Tablets 100's and 10's

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) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

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