Package Insert

OptiZinc™

Catalyst Health

COMPLEMENTARY MEDICINE – HEALTH SUPPLEMENT

This unregistered medicine has not been evaluated by the South African Health Product Regulatory Authority for its safety, quality or intended use.

SCHEDULING STATUS:

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1 NAME OF THE MEDICINE:
Catalyst Vitamin C with OptiZinc

2 QUALITIVE AND QUANTITIVE COMPOSITION:

Active ingredients:	Per capsule	Per dose	% NRV*
L-Ascorbic acid (Vitamin C)	500 mg	1000 mg	1000 %
OptiZinc (providing elemental Zinc)	10 mg	20 mg	182 %
Cholecalciferol (Vitamin D3)	12,5 µg	25 µg	167 %

*Nutrient Reference Values (NRVs) for individuals 4 years and older.
Sugar free.

3 PHARMACEUTICAL FORM:
White veggie capsule.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications:
Catalyst Vitamin C with OptiZinc assists in providing support by boosting the body's immune system to fight infections such as cold and flu. **Catalyst Vitamin C with OptiZinc** is an antioxidant and promotes physical well-being.

4.2 Posology and method of administration:
Adults and children over the age of 12 years, take 2 capsules daily or as advised by your healthcare practitioner.
For oral use.

4.3 Contraindications:
If you suffer from a chronic medical condition, only use large doses of vitamin C under the supervision of your healthcare practitioner. If you have a history of kidney stones, avoid using large doses of vitamin C.

Catalyst Vitamin C with OptiZinc must not be used in patients with:
- Hypersensitivity to the active substances (vitamin C, zinc, vitamin D3) or to any of the excipients listed in section 6.1
- Hypercalcaemia and/or hypercalciuria.
- Nephrolithiasis (renal calculi).
- Hypervitaminosis.
- Severe renal impairment.

4.4 Special warnings and precautions for use:
Discontinue the use of this product where there is sensitivity towards any of the ingredients. Use with caution if you are suffering from renal impairment.
Caution is required in patients receiving treatment for cardiovascular disease

Patients with sarcoidosis should be monitored for calcium content in the serum and urine.

Medical supervision is required whilst on treatment to prevent hypercalcaemia.

4.5 Interaction with other medicines and other forms of interaction:
If you are using chronic prescription medication, use large doses of vitamin C under the supervision of your healthcare practitioner.
Phosphate infusions should not be administered to lower hypercalcaemia or hypervitaminosis D because of the dangers of metastatic calcification.

Patients treated with cardiac glycosides may be susceptible to high calcium levels and should have ECG parameters and calcium levels monitored.

Simultaneous administration of benzothiadiazine derivatives (thiazide diuretics) should be monitored.

4.6 Fertility, pregnancy, and lactation:
Do not use if you are pregnant or breastfeeding.

4.7 Effects on ability to drive and use machines:
None.

4.8 Undesirable effects:
Discontinue the use of this product where there is sensitivity towards any of the ingredients.

4.9 Overdose:
Large doses of Vitamin C will cause diarrhoea.

5 PHARMACOLOGICAL PROPERTIES:
5.1 Pharmacodynamic properties:
D 34.12 Complementary Medicine: Health Supplement – Multiple Substance Formulation
ATC code: A 11A A03

Mechanism of action:
Vitamin C is a water-soluble vitamin found in fresh fruits and vegetables. Vitamin C has a role in several physiological functions. Vitamin C is also involved in a variety of metabolic processes including oxidation-reduction reactions and cellular respiration, carbohydrate metabolism, synthesis of lipids and proteins, catabolism of cholesterol to bile acids, and iron metabolism. Vitamin C is probably best known for its effects as an antioxidant and its role in maintaining proper immune function.
Vitamin D3 is easily absorbed in the small intestine. Vitamin D3 is produced within the skin under the influence of UV radiation, including sunlight. In its biologically active form, Vitamin D3 stimulates intestinal calcium absorption, incorporation of calcium into the osteoid, and release of calcium from bone tissue. In the small intestine it promotes rapid and delayed calcium uptake. The passive and active transport of phosphate is also stimulated. In the kidney, it inhibits the excretion of calcium and phosphate by promoting tubular resorption. The production of parathyroid hormone (PTH) in the parathyroids is inhibited directly by the biologically active form of Vitamin D3. PTH secretion is inhibited additionally by the increased calcium uptake in the small intestine under the influence of biologically active Vitamin D3. Vitamin D3 and other forms of vitamin D are excreted in faeces and urine.

5.2 Pharmacokinetic properties:
No vitamin C was excreted in urine of six of seven volunteers until the 100 mg dose. At single doses of 500 mg and higher, bioavailability declined, and the absorbed amount was excreted. Oxalate and urate excretion were elevated at 1000 mg of vitamin C daily compared to lower doses.
Vitamin D3 from nutritional sources is almost completely absorbed from within the gastrointestinal tract in the presence of dietary lipids and bile acids. Vitamin D3 is stored in fat cells and its biological half-life is approximately 50 days.

5.3 Preclinical safety data:
Not applicable.

6 PHARMACEUTICAL PARTICULARS:
6.1 List of excipients:
Microcrystalline cellulose MCC.

6.2 Incompatibilities:
Not known.

6.3 Shelf life:
24 months.

6.4 Special precautions for storage:
Store at or below 25 ºC. Protect from light and moisture. Keep out of reach of children.

6.5 Nature and contents of container:
Labelled, amber HDPE container and white flip top lid with 60 white veggie capsules.

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of such products:
No special requirements.

7 THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
LeBasi Pharmaceuticals (Pty) Ltd
San Domenico Building, Unit 6
10 Church Street
Durbanville 7550

8 REGISTRATION NUMBER:
To be allocated upon registration.

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION:
Not applicable.

10 DATE OF REVISION OF TEXT:
July 2020

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