

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

BONVIT COMPLETE

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Component 1: Multivitamin and mineral capsule

Ingredients	Per capsule
Calcium (Calcium carbonate)	230 mg
Vitamin C (Calcium ascorbate)	50 mg
Calcium (Calcium ascorbate)	7,69 mg
Vitamin B3 (Nicotinamide)	10 mg
Iron (Ferrous fumarate)	10 mg
Vitamin B1 (Thiamine mononitrate)	3 mg
Vitamin B2 (Riboflavin)	2 mg
Vitamin B6 (Pyridoxine hydrochloride)	1 mg
Magnesium (Magnesium oxide)	0,5 mg
Copper (Copper glycinate 10 %)	0,15 mg
Glycine (Copper glycinate 10%)	53,2 ug
Zinc (Zinc oxide)	0,085 mg
Potassium (Potassium phosphate monobasic)	0,084 mg
Manganese (Manganese sulphate monohydrate)	0,05 mg
Molybdenum (Molybdenum glycinate 2 %)	0,025 mg
Glycine (Molybdenum glycinate 2%)	5,9 ug
Iodine (Potassium iodide)	0,01 mg
Potassium (Potassium iodide)	0,0031 mg
Vitamin A (Vitamin A palmitate)	2666 IU
Vitamin D3 (Vitamin D3 100 CWS)	400 IU
Folic Acid (Folic acid BP)	500 ug
Vitamin B12 (Cyanocobalamin 0,1 %)	2 ug

Component 2: Calcium tablet

Ingredients	Per tablet
Calcium (Calcium Carbonate)	500 mg
Magnesium (Magnesium Carbonate)	125 mg
Vitamin D3 (Cholecalciferol)	400IU

Component 3: Omega capsule

Ingredients	Per capsule
Total Pharmaceutical Grade Fish oil, from tuna and deep marine fish oil providing:	823 mg
Docosahexaenoic Acid (DHA)	261 mg
Eicosapentaenoic Acid (EPA)	92 mg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Component 1: Multivitamin & mineral soft gel capsule: red oblong soft gel capsules.

Component 2: Calcium tablet: yellow oblong coated tablet

Component 3: Omega-3 Soft Gel Capsule: yellow oblong, clear soft gel capsule.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

BONVIT COMPLETE is a health supplement that provides the body with vitamins and minerals for the maintenance of good health.

4.2 Posology and method of administration

Adults and children 18 years and older: Take one multivitamin and mineral capsule (red), one calcium tablet (yellow) and one omega-3 soft gel capsule (clear yellow capsule) daily with food, or as directed by a healthcare provider.

The daily dosage can be taken all at once, or incrementally throughout the day.

4.3 Contraindications

- Patient with hypersensitivity to any of the active or inactive ingredients.
- Patients with hypercalcaemia, hypercalciuria, renal impairment, renal calculi or sarcoidosis.
- Patients with renal osteodystrophy with hyperphosphatemia (a bone disease caused by the incorrect functioning of the kidneys)

4.4 Special warnings and precautions for use

- Use with caution in patients with haemorrhagic disorders or in patients using medication affecting blood coagulation, such as anticoagulants. (see **INTERACTIONS**)
- BONVIT COMPLETE contains small amounts of sorbitol and glycerol which may have an effect on the glycaemic control of patients with *Diabetes Mellitus*. Patients with the rare hereditary condition of sorbitol or glycerol intolerance should not take this medicine.
- Use with caution in patients with hypophosphatemia or hyperphosphatemia.
- Use with caution in patients with heart disease.
- Use in children under the age of 18 years is at the discretion of a healthcare professional.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed on BONVIT COMPLETE. The following interactions are noted on monographs of the active ingredients:

- Antacids should be taken at least 2 hours before or after BONVIT COMPLETE, as they may reduce the absorption of vitamins and minerals.
- Anticoagulants/Antiplatelets: there is an increased risk of bleeding with concurrent use of medicines containing omega-3 and/or magnesium.
- Calcium-channel blockers: calcium supplements should be used with caution due to an antagonistic effect.
- Calcium can chelate and prevent the absorption of some medicines such as tetracyclines, quinolones, bisphosphonates, anti-retrovirals, levothyroxine and verapamil. Doses should be separated by at least 4 hours.
- Digoxin: administration of high doses of calcium increases the risk of cardiac arrhythmias. Magnesium may reduce the absorption of digoxin and thereby reduce its therapeutic effects.
- Oestrogen: concurrent use may cause hypercalcaemia.
- Gabapentin: concurrent use with magnesium reduces the absorption of gabapentin.
- Levodopa/Carbidopa: magnesium may reduce the effectiveness of levodopa/carbidopa if taken together.
- Potassium sparing diuretics: magnesium levels may increase with concurrent use.
- Sulfonylureas: concomitant administration with magnesium may enhance absorption and effect of sulfonylureas (e.g. glibenclamide)
- Thiazide diuretics: concurrent use may increase serum calcium levels. Serum calcium levels should be monitored.

- Thyroid medicines: Calcium can interfere with thyroid hormone replacement treatment. Separate calcium and thyroid medications by at least 4 hours

4.6 Fertility, pregnancy and lactation

Safety of BONVIT COMPLETE during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

The effects on ability to drive and use machines has not been studied.

4.8 Undesirable effects

Possible side effects include

- gastrointestinal discomfort (nausea, vomiting, heartburn, abdominal pain, bloating, dyspepsia, diarrhoea, constipation)
- eructation (belching) associated with a fishy taste in the mouth

4.9 Overdose

Symptoms of overdosage include stomach upset, nausea, diarrhoea or constipation

Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Health Supplement
D34.12 Multiple substance formulation

5.2 PHARMACOLOGICAL ACTION

- B-vitamins help to metabolise carbohydrates, fats and proteins, contribute to normal psychological function, normal functioning of the nervous system, maintenance of normal mucous membranes, maintenance of normal skin, regulation of hormonal activity, normal function of the heart, and the reduction of tiredness and fatigue.
- Calcium and Vitamin D contribute to the maintenance of normal muscle function and help in the development of healthy bones and teeth.
- Copper and Vitamin C are antioxidants which contribute to the protection of cells from oxidative stress and to normal function of the immune system.
- Folic Acid helps to form red blood cells and contributes to maternal tissue growth during pregnancy.
- Iron contributes to normal formation of red blood cells and haemoglobin and their proper function, normal oxygen transport in the body, cognitive function and immune system function.
- Magnesium contributes to normal electrolyte balance, muscle function, psychological function, and the reduction of tiredness and fatigue.
- Vitamin A contributes to the maintenance of good eyesight, skin, membranes and immune function.
- Omega-3 contains Eicosapentaenoic Acid (EPA) and Docosahexaenoic Acid (DHA) which help to support cognitive health and brain function.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Component 1: Multivitamin & mineral capsule: beeswax, lecithin, sunflower seed oil, unsaturated oil (hardened). Capsule: cochineal red, bovine gelatine, glycerine, iron oxide black, purified water, simethicone, titanium dioxide. Contains sugar: glycerol 0,111 g and sorbitol 0,013 g per capsule.

Component 2: Calcium tablet: beeswax, colloidal silica, magnesium stearate, maize starch, maltodextrin, opadry yellow, povidone, silicon dioxide, sodium starch glycolate, stearic acid.

Component 3: Omega-3 softgel capsule: alpha-tocopherol (covitol), gelatine, lemon flavour, simethicone, purified water. Contains sugar: glycerol 0,11 g and sorbitol 0,013 g/capsule.

6.2 Incompatibilities

Unknown

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C. Keep bottle tightly closed to protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

Blister packs with 10 capsules/tablets, packed in cartons of 30.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd
15E Riley Road, Bedfordview, 2007
Tel: (011) 087 0000
www.inovapharma.co.za

8 REGISTRATION NUMBER

To be allocated

9 DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

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