

PROFESSIONAL INFORMATION
NATIVA COMPLEX® COQ10 PLUS capsules

- Complementary Medicine.
- D.34.12, Health Supplements – Multiple substance formulation.
- This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS
[S0]

1. NAME OF THE MEDICINE
NATIVA COMPLEX® COQ10 PLUS
(capsules)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each capsule contains:

Active ingredients	Per capsule (maximum daily dose)	% NRV* per maximum daily dose
Coenzyme Q10 (ubidecarenone)	150 mg	*
Magnesium oxide providing magnesium (elemental)	132.67 mg 80 mg	19 %
Selenium glycinate providing: selenium (elemental) glycine	5 mg 100 µg 4.9 mg	 182 % *
Cholecalciferol (vitamin D3)	500 IU (12.5 µg)	83 %

*Nutrient reference values for adults and children older than 4 years.

*NRV not established.

Nativa Complex® CoQ10 Plus is sugar and preservative free.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Size 0 capsule, gelatine hard. Nativa Complex® CoQ10 Plus capsules are red.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Nativa Complex® CoQ10 Plus capsules contains coenzyme Q10 to help maintain and support cardiovascular health. Coenzyme Q10 functions as an antioxidant contributing to the protection of cells from oxidative stress. Nativa Complex® CoQ10 Plus capsules also contains vitamin D3, magnesium and selenium for the maintenance of good health. A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance. Efficacy of support may vary between users.

4.2 Posology and method of administration

The recommended daily dosage is

Adults 18 years and older:

One (1) capsule per day, after a meal, with a glass of water. Advise the patient to discontinue use two (2) weeks prior to surgery (see 4.5).

If the patient forgets to take Nativa Complex® CoQ10 Plus

Advise the patient to take the missed dose when they remember. Do not take a double dose to make up for forgotten individual doses.

Taking Nativa Complex® CoQ10 Plus with food, drink and alcohol

There is no known interaction between contents of Nativa Complex® CoQ10 Plus and food, drink and alcohol. Advise the patient to not take dosage at the same time as other medications (see 4.5).

4.3 Contraindications

- Must not be given to patients with known hypersensitivity to any of the ingredients of Nativa Complex® CoQ10 Plus (see section 6.1 List of excipients). Patients should be advised to consult their medical practitioner if in doubt.
- Patients taking any chronic medication should not use this product without consulting their medical practitioner.

4.4 Special warnings and precautions for use

- Patients with bleeding disorders or taking anticoagulants/blood thinners or antiplatelet medication should use this product with caution (see 4.5).
- Patients taking blood pressure medication should consult a relevant healthcare provider before use (see 4.5).
- Nativa Complex® CoQ10 Plus might interfere with blood pressure control during and after surgical procedures. It is advisable that patients discontinue use two (2) weeks prior surgery (see 4.5).
- Use with caution in patients with a history of non-melanoma skin cancer as Nativa Complex® CoQ10 Plus capsules contains selenium.
- Patients with renal calculi, renal impairment, kidney disease, histoplasmosis, hyperparathyroidism, lymphoma, sarcoidosis, tuberculosis or a history of these conditions, should use this product with caution due to the potential increase of calcium levels as Nativa Complex® CoQ10 Plus contains vitamin D3.
- Nativa Complex® CoQ10 Plus contains vitamin D3 which can aggravate conditions such as hypercalcaemia and/or hypercalcaemia which can contribute to arteriosclerosis.
- Nativa Complex® CoQ10 Plus contains vitamin D3 which can worsen hyperphosphatemia and hypercalcaemia.
- Do not exceed the daily recommended dose.
- Do not use after the date of expiry.

Porphyria

Safety has not been established.

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed on Nativa Complex® CoQ10 Plus, see below interactions with individual ingredients.

Active ingredient	Medicine	Description
Coenzyme Q10, magnesium and selenium	Blood thinners (anticoagulant or anti-platelet medication) e.g., warfarin	May have a blood thinning effect, increasing the risk of bleeding.
Coenzyme Q10	Antihypertensive medication	May have additive hypotensive effects. Coenzyme Q10 containing products such as Nativa CoQ10 Complex® might interfere with blood pressure control during and after surgical procedures.
Magnesium	Antibiotics	The absorption of antibiotics may be decreased. Oral antibiotics should be taken at least two (2) hours before, or four (4) hours after Nativa Complex® CoQ10 Plus or similar supplements.
Magnesium	Bisphosphates	May decrease bisphosphonate absorption. Advise patients to separate doses of Nativa Complex® CoQ10 Plus and these medicines by at least two (2) hours.
Magnesium	Digoxin	May reduce absorption of digoxin.
Magnesium	Levodopa/carbidopa (Sinemet®)	May reduce the bioavailability of levodopa/carbidopa.
Magnesium	Sulfonylureas	May increase the systemic absorption of sulfonylureas, increasing effects and side effects.
Magnesium	Potassium sparing diuretics	Potassium sparing diuretics have magnesium sparing properties. Increased magnesium levels could result with concomitant use of potassium sparing diuretics and supplementation.
Vitamin D3	Calcium supplements	Vitamin D3 has the potential to increase the absorption of calcium when used concomitantly with calcium supplements.

4.6 Fertility, pregnancy and lactation

Pregnancy

Safety of some of the ingredients for use during pregnancy has not been established (see 4.3), therefore this product should not be used in patients who are pregnant.

Breastfeeding

Safety of some of the ingredients for use during lactation (breastfeeding) has not been established (see 4.3), therefore this product should not be used if patients are lactating (breastfeeding).

Fertility

There are no known effects of Nativa Complex® CoQ10 Plus on fertility.

4.7 Effects on the ability to drive and use machines.

Based on the side effect profile, Nativa Complex® CoQ10 Plus should not affect your ability to drive or operate machinery. It is not always possible to predict to what extent Nativa Complex® CoQ10 Plus may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which Nativa Complex® CoQ10 Plus affects them.

4.8 Undesirable effects

Nativa Complex® CoQ10 Plus capsules are generally well tolerated with the occurrence of adverse events unknown. Patients experiencing any side effects or sensitivity to any of the ingredients, should discontinue use. Adverse reactions reported in the literature are listed below, by system organ class and frequency. Frequencies are defined as:

- very common (≥1/10)
- common (≥1/100 to <1/10)
- uncommon (≥1/1,000 to <1/100)
- rare (≥1/10,000 to <1/1,000)
- very rare (<1/10,000)
- not known (cannot be estimated from the available data)

System Organ Class	Frequency	Adverse Event
Immune system disorders	Not known	Hypersensitivity reactions or anaphylaxis, symptoms include: difficulty breathing or swallowing, angioedema, itchy throat, urticaria and itching.
Endocrine	Not known	Clinical studies have shown an association between the increased intake of selenium, either as a supplement or in the diet, and the risk for developing type 2 diabetes.
Nervous system disorders	Not known	Headache and dizziness.
Eye disorders	Not known	Photophobia (sensitivity to light).
Gastrointestinal disorders	Not known	Abdominal discomfort, diarrhoea, heartburn, nausea, vomiting, appetite suppression, flatulence and dry mouth.
Skin and subcutaneous tissue disorders	Not known	Hypersensitivity reaction (skin rash and itching).

If symptoms persist, or if any adverse reactions occur, advise the patient to consult a healthcare provider.

Reporting of suspected adverse reactions

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website.

4.9 Overdose

Symptoms

See 4.8 Undesirable effects

In overdose, side effects can be precipitated and/or be increased.

There is no evidence that this product can lead to an overdose when used as recommended.

Due allowance should always be made for intake of these vitamins from other sources.

Vitamin D intoxication can occur when vitamin D supplements are taken orally in excessive doses.

Treatment

If an accidental overdose occurs, treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: D.34.12. Complementary Medicine: Health Supplements – Multiple substance formulation

Coenzyme Q10

Numerous physiological processes are affected by coenzyme Q10 such as sulphide oxidation, control of the mitochondrial permeability transition pore and membrane stabilisation and the movement of protons and calcium ions across biological membranes. Coenzyme Q10 is also a cofactor in many metabolic pathways, particularly the production of adenosine triphosphate (ATP) in oxidative respiration. It is proposed that the general and cardiovascular benefits of coenzyme Q10 supplementation are due to its antioxidant effect and physiological fundamental role in mitochondrial function and cellular bioenergetics.

Magnesium

Extracellular magnesium is essential for maintaining nerve and muscle electrical potentials, as well as, transmitting nerve impulses across neuromuscular junctions. Magnesium plays a crucial role in physiological processes due to its pharmacodynamic properties, which involve its function as a cofactor in over 300 enzymatic reactions, particularly those related to energy production, muscle function, and protein synthesis. Moreover, magnesium has anti-inflammatory properties and is essential for maintaining healthy nerve function, supporting cardiovascular health, and promoting better sleep.

Selenium

Selenium is an essential trace element which is a cofactor in various enzymes in the body. More than 25 selenium containing proteins and protein subunits have been identified and most of the clinical and biochemical effects of selenium can be attributed to their activity. Further effects of selenium are due to selenium-containing glutathione peroxidase and selenium protein P. Glutathione peroxidase forms part of the antioxidant protection mechanism of the cell. As a constituent of glutathione peroxidase, selenium can delay the lipid peroxidation rate and resultant damage to the cell wall. Glutathione peroxidase affects the metabolism of prostacyclines, leukotrienes and thromboxanes.

Vitamin D3

Vitamin D is a fat-soluble vitamin and appears to have immunological activity. It is also an essential vitamin for the proper regulation of calcium and phosphate homeostasis and bone mineralisation.

5.2 Pharmacokinetic properties

Coenzyme Q10

Absorption: coenzyme Q10 enters the lymphatic system after being absorbed from the small intestine before reaching the circulation. Absorption is restricted due to its hydrophobicity and high molecular weight of around 864 Daltons. The absorption is enhanced in the presence of a high-lipid diet and is decreased in the presence of an empty stomach. Coenzyme Q10 is detected in plasma about 4 hours after oral ingestion, and peak levels occur in 5 to 10 hours. Investigations have shown that an area under the curve (AUC) of 11.51 µg·h/ml and a Cmax of 0.32 µg/ml at a period of 7.9 h are typical.

Distribution: coenzyme Q10 can enter the brain and is dispersed throughout the body's tissues; distributed to the inner mitochondrial membrane of cells in cardiac tissue and sperm, and is also found in mononuclear cells, platelets, semen and lipoproteins. It can also be taken up by the liver and transferred primarily to very low-density lipoproteins (VLDL) and redistributed from the liver to the systemic blood. Intravenously administered coenzyme Q10 in preclinical experiments volume of distribution was reported to be 20.4 l/kg. This indicates that it can penetrate deeply into organs and tissues. Steady-state is reached after approximately 14 days, when plasma levels are around 3 µg/mL with non-crystalline coenzyme Q10 in lipid softgel capsules, 2.5 µg/mL with crystals in lipid softgel capsules, and 1.5 µg/mL with powder in hard-shell capsules. Typically, tissues with high energy needs or metabolic activity such as the heart, kidney, liver, and muscle, contain larger quantities of coenzyme Q10.

Excretion: coenzyme Q10 is primarily eliminated through the bile with an elimination half-life of approximately 34 hours. Following oral delivery, coenzyme Q10 and a minor amount of its metabolites account for more than 60 % of the dose that is eliminated in the stool. Only 6.3 % of the total dose of coenzyme Q10 is found in the urine, where it is bound to the protein saposin B.

Magnesium

Absorption: absorbed throughout the gastrointestinal tract with an estimate of one third of dietary magnesium absorbed. Efficiency of absorption depends partly on magnesium stores in the body. The average absorption of supplements is 38 %, however it may vary from 65 % in people with low magnesium stores to 11 % in those with high magnesium stores. Plasma concentrations peak at 4 hours after a dose.

Distribution: about 25 % of magnesium is contained in the body, which is divided in almost equal portions between soft tissue and the skeleton. Roughly a third of skeletal magnesium is found at the surface of the bone and acts as a reservoir to maintain extracellular magnesium concentrations. The remaining two-thirds is tightly bound to bone and is not readily available as a source of magnesium. Extracellular magnesium makes up only 1 % of total body magnesium. In plasma, about 30 % is bound to plasma proteins, 55 % is ionized or free, and 15 % is complexed to anions.

Excretion: magnesium is excreted primarily via the kidneys and averages only 3 % to 5 % of the filtered load. Excretion ranges from 10 to 5000 mg over a 24-hour period. Urinary magnesium and pH are known to modulate urinary calcium excretion, however, the exact mechanism is unknown.

Selenium

Absorption: diet is the major source of selenium, and approximately 80 % of dietary selenium is absorbed, depending on the type of food consumed. Selenium is absorbed via the gastrointestinal tract, crosses the intestinal barrier to reach the blood circulation, and is then distributed to the different tissues of the body.

Distribution: selenium is found in various tissues with approximately 28 % to 46 % of the total body's selenium content is found in skeletal muscle. The kidney accumulates the highest level of selenium and is the major source of plasma glutathione peroxidase (GSH-Px).

Metabolism: selenium metabolism by the brain differs from other organs in that at times of deficiency, the brain retains selenium to a greater extent.

Excretion: selenium from food and supplements is mainly excreted in the urine as 1-beta-methylseleno-N-acetyl-L-α-galactosamine and trimethylselenonium. Some selenium may be excreted in faeces and lungs.

Vitamin D3

Absorption: vitamin D3 is well absorbed from the gastrointestinal tract and can be stored in adipose tissue. Each µg of vitamin D3 daily may increase serum 25 hydroxyvitamin D concentrations by an average of 0.78 ng/mL.

Distribution: dietary vitamin D3 is transported primarily by chylomicron, which allows vitamin D3 to be distributed to peripheral tissues. If it is not taken up by peripheral tissue, vitamin D3 is transported to the liver, where it is converted to calcitriol.

Metabolism: vitamin D3 is biologically inert and requires hydroxylation in the body to form the active metabolite, calcitriol. Vitamin D3 is hydroxylated in the liver to form calcifediol and thereafter, undergoes further hydroxylation in the kidneys to form the active metabolite calcitriol.

Excretion: vitamin D3 and its metabolites are primarily excreted in the bile and faeces, with only small quantities appearing in the urine.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatin capsule (capsule constituents: bovine gelatine, allura red (E129), titanium dioxide (E171))

Colloidal silicon dioxide

Magnesium stearate

Maize starch

6.2 Incompatibilities

None known

6.3 Shelf life

24 months

6.4 Special precautions for storage

- Store all medicines out of reach of children.
- Store in a dry place at or below 25 °C.
- Protect from light and moisture.
- Keep in original packaging until use.
- Close cap firmly after use.
- Do not refrigerate.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6.5 Nature and contents of container

Nativa Complex® CoQ10 Plus are red capsules.

Nativa Complex® CoQ10 Plus is available in a white high density polyethylene plastic container with a red flip-top cap. It contains 30 capsules and includes a patient information leaflet in a printed unit carton.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Nativa (Pty) Ltd

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Customer care line: 0860 628 482

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8. REGISTRATION NUMBER(S)

To be allocated

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated

10. DATE OF REVISION OF THE TEXT

January 2025