

The Real Thing Nutra-C® Combo Capsules

Complementary Medicine, Health Supplement.

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

THE REAL THING NUTRA-C® COMBO CAPSULES, vitamin C 334 mg, citrus bioflavonoid 34 mg, selenium 0,067 mg, zinc 5 mg, *Curcuma longa* (turmeric) 34 mg and *Piper nigrum* (black pepper) 1,6 mg per capsule.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each THE REAL THING NUTRA-C® COMBO CAPSULES contains:

	Per capsule	Per 3 capsules
Nutra-C® providing	474 mg	1 422 mg
* Ascorbic acid (vitamin C) (from calcium ascorbate)	334 mg	1 000 mg
Citrus bioflavonoid	34 mg	100 mg
Selenium amino acid chelate providing	34 mg	100 mg
* Selenium	0,067 mg	0,20 mg
Zinc citrate providing	20 mg	60 mg
* Zinc	5 mg	15 mg
<i>Curcuma longa</i> (turmeric)	34 mg	100 mg
<i>Piper nigrum</i> (black pepper)	1,70 mg	5,10 mg
Equivalent to piperine	1,58 mg	4,75 mg

* Indicates elemental quantities calculated.

Excipients include dicalcium phosphate, magnesium stearate, silicone dioxide and a veggie capsule shell. The capsules are sugar free.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

THE REAL THING NUTRA-C® COMBO CAPSULES is a yellow to orange powder with fine dark specks, in a size 00 clear vegetable capsule.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

THE REAL THING NUTRA-C® COMBO CAPSULES help to maintain the body's immune function.

It helps to protect body cells from oxidative damage caused by free radicals.

It helps to metabolise carbohydrates, fats and proteins.

It helps in the development and maintenance of bones, cartilage, teeth and gums.

It helps in connective tissue formation.

It helps to relieve inflammation.

It helps in wound healing.

It helps to maintain healthy skin.

As a supplement it is a factor in the maintenance of good health.

It is indicated in adults.

4.2 Posology and method of administration

Adults: Take three capsules orally daily. Take with food to reduce zinc and iron interfering with each other's absorption and also to reduce gastrointestinal side effects.

Paediatric population

Selenium, turmeric, citrus bioflavonoids and black pepper are not suitable for oral use in children.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

If a patient has been diagnosed with any of the conditions listed below the patient should be advised to consult a health care practitioner prior to taking THE REAL THING NUTRA-C® COMBO CAPSULES.

It should be given with caution to patients with hyperoxaluria. Large amounts of vitamin C (above 1g per day) may increase the risk of kidney stone formation in those with a history of oxalate kidney stones.

Use with caution in patients with gallstones or gallbladder disease or bile duct obstruction as turmeric can cause gallbladder contractions.

Use turmeric with caution in patients with stomach ulcers or excess stomach acid.

If a patient is taking turmeric for relief of inflammation, advise the patient to consult a health care provider if symptoms persist or worsen.

4.5 Interaction with other medicines and other forms of interaction

Other products affecting THE REAL THING NUTRA-C® COMBO CAPSULES:

Prolonged thiazide therapy might deplete tissue zinc.

Calcium, phosphorous or phytate-containing foods (found in grains e.g. maize, corn and sorghum; legumes; seeds e.g. sunflower and pumpkin seeds; rice; and soy) can reduce the absorption of zinc.

Penicillamine forms chelates with zinc, thereby increasing zinc excretion, but also increasing intestinal zinc absorption. Doses of penicillamine and zinc should be separated by 1-2 hours.

THE REAL THING NUTRA-C® COMBO CAPSULES affecting other products:

Vitamin C may increase the absorption of iron in iron deficiency states.

Citrus bioflavonoids may alter the effectiveness of prescription medication. Advise the patient to consult a health care practitioner prior to use.

Quinolones form complexes with zinc in the gastrointestinal tract (GIT), reducing absorption of both when taken at the same time.

Tetracyclines form complexes with zinc in the GIT, which can reduce absorption of both when taken at the same time.

Zinc forms an insoluble complex with penicillamine, interfering with penicillamine absorption and activity.

Advise patients to consult a health care practitioner before taking turmeric if they are taking antiplatelet medication or blood thinners.

Turmeric's antioxidant effects may reduce the activity of chemotherapeutic medicines that generate free radicals, including alkylating agents, antitumour antibiotics and topoisomerase I inhibitors.

Turmeric may have antiplatelet effects and should be used with caution in combination with anticoagulants (e.g. warfarin) and antiplatelet medicines.

Turmeric and antidiabetic medicines may have a cumulative effect of increasing the risk of hypoglycaemia.

Zinc may lower blood glucose levels and may have additive effects in patients treated with antidiabetic agents.

Selenium has antiplatelet effects and might cause excessive bleeding if used perioperatively. Discontinue selenium at least 2 weeks prior to elective surgical procedures.

Large amounts of zinc above 40mg per day can increase the risk of copper deficiency. Under some circumstances zinc and iron can interfere with each other's absorption. This competition for absorption is not significant when these supplements are taken with food.

4.6 Fertility, pregnancy and lactation

Vitamin C, selenium and zinc are safe to use during pregnancy and lactation. Vitamin C crosses the placenta and is excreted in breast milk.

Safety of citrus bioflavonoids, turmeric and black pepper during pregnancy and lactation has not been proven. Advise the patient to consult a health care practitioner before taking THE REAL THING NUTRA-C® COMBO CAPSULES during pregnancy and lactation.

A diet high in selenium might decrease sperm motility which theoretically could decrease male fertility. Conversely, selenium is required for testosterone biosynthesis and the formation and development of sperm. Male fertility appears to be improved by zinc.

4.7 Effects on ability to drive and use machines

THE REAL THING NUTRA-C® COMBO CAPSULES have no or negligible influence on these abilities.

4.8 Undesirable effects

Vitamin C, selenium and zinc are usually well tolerated, but large doses may cause diarrhoea and other gastrointestinal disturbances. Citrus bioflavonoids, turmeric and black pepper are generally well tolerated at recommended doses.

The most common adverse effects include -

Psychiatric disorders:

giddiness (rarely).

Nervous system disorders:

fatigue, headache, insomnia, sleepiness, vertigo (rarely).

Vascular disorders:

flushing, increased risk of bleeding

Gastrointestinal disorders:

nausea, vomiting, metallic taste in the mouth, tongue staining, esophagitis, heartburn, burning aftertaste, indigestion, dry mouth, mouth irritation, abdominal cramps, abdominal pain, gastrointestinal obstruction, diarrhoea, mild gastric discomfort, gastritis, epigastric burning, constipation, yellow hard stools, distension, gastroesophageal reflux and flatulence. Nutra-C® has a lower incidence of epigastric effects, gastrointestinal discomfort and digestive problems due to its gentler effect on the stomach compared with normal acidic vitamin C.

Skin and subcutaneous tissue disorders:

skin rash, pruritus (rarely), pitting oedema (rarely).

Frequencies of adverse effects are not known.

Citrus bioflavonoids are well tolerated.

Reporting of suspected adverse events

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA's publications:

<https://www.sahpra.org.za/Publications/Index/8>

Alternatively, suspected adverse reactions may be reported directly to the applicant, The Real Thing Food Supplements (Pty) Ltd at telephone 021-701 0244 or e-mail info@therealthing.co.za

4.9 Overdose

Large doses of vitamin C may cause diarrhoea and other gastrointestinal disturbances. Large doses of vitamin C may also result in hyperoxaluria and the formation of renal calcium oxalate calculi. All these effects are less likely during the intake of large doses of Nutra-C®.

Large doses of vitamin C are associated with deep vein thrombosis, cardiovascular mortality and carotid inner wall thickening. Large doses of vitamin C have resulted in haemolysis in patients with G6PD deficiency.

Large doses of selenium can cause symptoms of acute toxicity including nausea, vomiting, diarrhoea, abdominal pain, dermatitis, metallic taste, nail changes, fatigue, irritability, alopecia, impaired endocrine function, neurotoxicity, peripheral neuropathy, weight loss and a possible increased risk for type 2 diabetes.

Large doses of zinc may cause irritation and corrosion of the gastrointestinal tract, abdominal pain, watery diarrhoea, dehydration, epigastric pain and severe vomiting. Zinc may cause central nervous system symptoms including lethargy, fatigue, neuropathy, poor muscle co-ordination, dizziness and paraesthesia. Zinc may cause flu-like symptoms, including coughing. It can cause acute renal tubular necrosis and interstitial nephritis. Large doses of zinc taken over 6 weeks appear to impair immune response.

Treatment of overdosage is symptomatic and supportive. Due to the corrosive effect of zinc in overdosage treatment should include giving milk or alkali carbonates and activated charcoal. Avoid emetics or gastric lavage.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

It belongs to category D Complementary Medicines, Health Supplements, class 34.12

Multiple Substance Formulation.

THE REAL THING NUTRA-C® COMBO CAPSULES contain Nutra-C® which is calcium ascorbate, magnesium ascorbate and calcium threonate, a highly bioavailable form of vitamin C. It has the ability to increase vitamin C uptake in the cells with more ascorbate activity provided within the cells, resides in the body longer and is used more efficiently by cells and connective tissue. Nutra-C® is a chelated form of vitamin C for ease on the digestive system, with a neutral pH between 6-9, making it gentle on the stomach and safe for teeth enamel.

Vitamin C is one of the body's well-known antioxidants, and has a variety of beneficial physiological effects, as listed under therapeutic indications.

Citrus bioflavonoids provide antioxidant activity and thus work synergistically with Nutra-C®. Citrus bioflavonoids thereby help to protect the body from free radical damage.

Selenium is a metallic substance which is often attached to an organic molecule. At recommended doses it provides antioxidant activity.

Zinc is a biologically essential trace element and is the second most abundant trace element in the human body. It is a cofactor in many biological processes, plays a role in immune function, wound healing, growth and development, and many other physiological processes.

Turmeric has antioxidant properties. Turmeric helps to relieve inflammation.

Black pepper has antioxidant properties.

5.2 Pharmacokinetic properties

Vitamin C is well absorbed orally, and is widely distributed in body tissues. It is mostly excreted in urine.

Citrus bioflavonoids have low bioavailability and are excreted via urine.

Selenium is well absorbed from the gastrointestinal tract. It is stored in red blood cells, the liver, spleen, heart and nails and is converted in tissues to its metabolically active forms.

Selenium is excreted in the urine, and to a lesser extent in the faeces.

Zinc absorption is from the small intestine, mainly the jejunum. Absorption increases during states of low zinc levels. It is distributed throughout the body with highest concentrations in

muscle and bone. Metabolism takes place in the liver. It is primarily excreted in the faeces, with small amounts lost via the urine and perspiration.

Turmeric taken orally generally has low bioavailability, with absorption possibly increased by food. Significant metabolism occurs in liver and intestines. Excretion is mainly via faeces, and possibly urine.

There is insufficient reliable information available about black pepper.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients include –

- dicalcium phosphate
- magnesium stearate
- silicone dioxide
- vegetable capsule shell

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

A shelf life of 2 years is allocated when stored in a cool dry place at or below 25 °C.

6.4 Special precautions for storage

Keep container tightly closed. Protect against moisture and light.

6.5 Nature and contents of container

THE REAL THING NUTRA-C® COMBO CAPSULES are packed in a 200 ml amber glass bottle and non-child resistant 45 mm polyethylene black screw cap fitted with an aluminium foil heat-induction / pressure tamper-evident seal. A silica gel sachet is included in the bottle. The bottle contains 90 capsules. The bottle is packed in a round core carton fitted with a white insert lid.

6.6 Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

THE REAL THING FOOD SUPPLEMENTS (PTY) LTD

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