

The Real Thing Nutra[®] C 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[®] CAPSULES, vitamin C 500 mg and citrus bioflavonoid 50 mg per capsule.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

THE REAL THING NUTRA-C[®] CAPSULES contain:

	Per capsule	Per 2 capsules
Nutra-C [®] providing	710 mg	1 420 mg
* Ascorbic acid (vitamin C) from calcium ascorbate	500 mg	1 000 mg
Citrus bioflavonoid	50 mg	100 mg

Excipients include 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[®] CAPSULES is a fine cream coloured powder in a size 00 clear vegetable capsule.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

THE REAL THING NUTRA-C[®] CAPSULES help to protect body cells from oxidative damage caused by free radicals.

It helps to metabolise fats and proteins.

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

It helps in connective tissue formation.

It helps in wound healing.

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 two capsules orally daily.

Paediatric population

Citrus bioflavonoids 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

THE REAL THING NUTRA-C[®] CAPSULES should be given with caution to patients with hyperoxaluria. Large amounts of vitamin C (above 1g per day) may increase the risk of oxalate stone formation in those with a history of oxalate kidney stones.

4.5 Interaction with other medicines and other forms of interaction

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

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

4.6 Fertility, pregnancy and lactation

Vitamin C is safe to use during pregnancy and lactation. Vitamin C crosses the placenta and is excreted in breast milk. Safety of citrus bioflavonoids during pregnancy and lactation has not been proven. Advise the patient to consult a health care practitioner before taking THE REAL THING NUTRA-C® CAPSULES during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Vitamin C is usually well tolerated, but large doses may cause diarrhoea and other gastrointestinal disturbances. Citrus bioflavonoids are well tolerated at recommended doses.

The most common adverse effects include -

Nervous system disorders:

fatigue, headache, insomnia, sleepiness.

Vascular disorders:

flushing.

Gastrointestinal disorders:

nausea, vomiting, esophagitis, heartburn, abdominal cramps, gastrointestinal obstruction, diarrhoea.

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.

Frequencies of adverse effects are not known.

Citrus bioflavonoids are well tolerated.

Reporting of suspected adverse reactions

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.

Treatment of overdosage is symptomatic and supportive.

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® 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.

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients include –
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® CAPSULES are packed in a 200 ml amber glass bottle and non-child resistant 45 mm polyethylene black / white 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 60 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

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