

The Real Thing Chlorella Tablets

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 CHLORELLA TABLETS 200 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

	Per 1 tablet	Per 5 tablets
Chlorella (<i>Chlorella pyrenoidosa</i>) powder	200 mg	1 000 mg
Providing potassium	1,84 mg	9,20 mg
Providing vitamin K	1,42 microgram	7,11 microgram

Other ingredient includes magnesium stearate (vegetable). The tablets are sugar free.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

THE REAL THING CHLORELLA TABLETS are dark green round 9 mm tablets, having a characteristic herbal taste and odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

THE REAL THING CHLORELLA TABLETS is a nutritional supplement rich in nutrients and the antioxidants, β -carotene, ascorbic acid, α -tocopherol, lutein and chlorophylls. It has antioxidant activity. It is indicated in adults.

Supplementation should not replace a healthy, balanced and varied diet.

4.2 Posology and method of administration

Adults 18 years and older: Take 5 tablets (1 g chlorella) orally twice a day with a glass of water at meal times. It can be taken safely for up to 12 weeks.

Take it a few hours before or after taking other medications or natural health products.

Unless otherwise prescribed, do not exceed the stated dose.

Advise patient to consult a healthcare practitioner for prolonged use.

Paediatric population

Not suitable for children unless under the care of a relevant healthcare provider.

4.3 Contraindications:

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

If symptoms worsen or patient feels unwell, advise the patient to stop use immediately and consult a healthcare practitioner.

Chlorella might cause an allergic reaction in people sensitive to iodine because THE REAL THING CHLORELLA TABLETS may contain iodine.

4.5 Interactions with other medicines and other forms of interaction

THE REAL THING CHLORELLA TABLETS affecting other products:

Chlorella contains vitamin K, which may decrease the anticoagulant activity and hence the effectiveness of warfarin. Advise the patient to consult a healthcare practitioner prior to use if taking blood thinning medication.

Chlorella might have additive effects with photosensitizing medicines or herbs.

4.6 Fertility, pregnancy and lactation

Advise the patient to consult a healthcare practitioner before taking THE REAL THING CHLORELLA TABLETS during pregnancy or breastfeeding.

Possibly safe for use during pregnancy when taken orally and appropriately in medicinal amounts for up to approximately the 28th week of pregnancy.

Safety during breastfeeding has not been proven.

4.7 Effects on ability to drive and use machines

THE REAL THING CHLORELLA TABLETS has a minor influence on these abilities due to possible undesirable effects.

4.8 Undesirable effects

Orally chlorella is generally well tolerated. It is likely safe when used orally in the short term.

Summary of adverse events include -

Immune system disorders

Allergic reactions (common) including asthma. Anaphylaxis (rare).

Nervous system disorders

Fatigue (common).

Gastrointestinal disorders

Diarrhoea (common), constipation (common), abdominal cramping (common), flatus (common), nausea (common) especially during first two weeks of treatment. Stool discolouration (common).

Skin and subcutaneous tissue disorders

Photosensitivity reactions (common).

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 Holder of the Certificate of Registration, The Real Thing Food Supplements (Pty) Ltd at telephone 021-701 0244 or e-mail adr@therealthing.co.za

4.9 Overdose

None known. Treatment of overdosage is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

It belongs to category D Complementary Medicines, Health Supplements, class 34.13 Other. THE REAL THING CHLORELLA TABLETS contain broken green gem chlorella, which is a single-cell, green micro algae referred to as seaweed that lives in fresh water.

Chlorella provides a comprehensive spectrum of the nutrients the body requires for healthy growth and functioning. It contains chlorophyll, carotenoids, protein and amino acids, lipids such as omega 3 and 6 fatty acids, carbohydrates, fibre, nucleic acids, vitamins including B12, B6, methyl cobalamin, folate and vitamin K. It contains iron, trace elements such as zinc, copper and magnesium, and minerals. It also contains sporopollenin and numerous antioxidants such as beta-carotene, ascorbic acid, alpha-tocopherol, zeaxanthin and others. Chlorella has antioxidant properties. Carotenoids, a component of chlorella, appear to have free radical scavenging activity.

5.2 Pharmacokinetic properties

There is insufficient information available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Excipients include magnesium stearate (vegetable).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

THE REAL THING CHLORELLA TABLETS has a shelf life of 2 years when stored in a cool, dry place at or below 25 °C.

6.4 Special precautions for storage

Store in an airtight container, protected from light.

6.5 Nature and contents of container

THE REAL THING CHLORELLA TABLETS are packed in a sealed plastic bag inside a cardboard container with an inner aluminium liner, a metal base and top, and a tamper proof seal with a clear plastic lid. A silica gel sachet is included in the plastic bag. A foam sponge is located below the tablets in the container. The cardboard container contains 500 tablets. Alternatively, THE REAL THING CHLORELLA TABLETS are packed in a 200 ml amber glass bottle with a child resistant 45 mm polyethylene black screw cap fitted with an aluminium foil heat-induction or pressure tamper-evident seal. A silica gel sachet is included in the bottle. The bottle contains 500 tablets.

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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8 REGISTRATION NUMBER

(To be allocated)

9 DATE OF FIRST AUTHORISATION

(To be allocated).

10 DATE OF REVISION OF THE TEXT

This is the first edition.