

The Real Thing Green Power 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 GREEN POWER CAPSULES contains *Arthrospira platensis* (spirulina) 233,3 mg, *Chlorella pyrenoidosa* (chlorella) 233,3 mg, *Hordeum vulgare* (barley grass) 33,3 mg, *Triticum aestivum* (wheatgrass) 33,3 mg, *Medicago sativa* (alfalfa powder) 16,7 mg, *Ascophyllum nodosum* (rockweed) 6 mg, *Laminaria digitata* (kelp) 3,5 mg per capsule.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

THE REAL THING GREEN POWER CAPSULES contains:

	Per capsule	Per 3 capsules
<i>Arthrospira platensis</i> (spirulina) [whole algae]	233,3 mg	700 mg
<i>Chlorella pyrenoidosa</i> (chlorella) [broken cells, full algae]	233,3 mg	700 mg
<i>Hordeum vulgare</i> (barley grass) [leaf]	33,3 mg	100 mg
<i>Triticum aestivum</i> (wheatgrass) [leaf]	33,3 mg	100 mg
<i>Medicago sativa</i> (alfalfa powder) [leaf]	16,7 mg	50 mg
<i>Ascophyllum nodosum</i> (rockweed) [lamina]	6 mg	18 mg
Providing iodine	5,17 microgram	15,51 microgram
<i>Laminaria digitata</i> (kelp) [lamina]	3,5 mg	10,5 mg
Providing iodine	19,95 microgram	59,85 microgram

The inactive ingredients include magnesium stearate (palm oil) and hypromellose (vegetable) capsule shell. The capsules are sugar free.

For full list of excipients list of excipients, see section 6.1.

The capsules provide iodine 25,12 microgram per capsule (75,36 microgram per 3 capsules) and potassium 441 microgram per capsule (1 322 mg per 3 capsules).

3 PHARMACEUTICAL FORM

THE REAL THING GREEN POWER CAPSULES is a clear hard capsule shell (vegicap), size 00, containing a fine green powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

THE REAL THING GREEN POWER CAPSULES is a source of –

- Antioxidants;
- Vitamins and/or minerals;
- Protein;
- Essential amino acids.

As a health supplement it is a factor in the maintenance of good health. Supplementation should not replace a healthy, balanced and varied diet.

4.2 Posology and method of administration

Adults 18 years and older: Take 3 (three) capsules orally once a day with a full glass of water or fruit juice, or as prescribed by the patient's healthcare practitioner. Advise the patient to not exceed the daily dosage level or to use beyond 6 months without consulting a relevant health care provider.

Advise patients to take it a few hours before or after taking other medications or natural health products.

Discontinue use at least two weeks prior to elective surgery due to spirulina possibly affecting blood glucose control during surgery.

Paediatric population

THE REAL THING GREEN POWER CAPSULES is not suitable for use in children unless under the care of a relevant healthcare provider.

4.3 Contraindications

Advise the patient not to take this product if allergic or hypersensitive to any of the active ingredients or excipients. Do not take it if pregnant, breastfeeding or if patient has a history of systemic lupus erythematosus due to alfalfa.

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 relevant health care practitioner.

Spirulina can have hypoglycaemic effects in patients with diabetes.

Spirulina has been shown to stimulate the immune system. Advise patients with autoimmune diseases to consult a health care practitioner prior to taking spirulina.

Chlorella may contain iodine and is a source of potassium. Kelp and rockweed are sources of iodine and potassium. This product may cause an allergic reaction in those sensitive to iodine. Ingesting more than 150 microgram iodine per day can cause hypothyroidism, hyperthyroidism or exacerbate existing hyperthyroidism. Use kelp with caution in renal insufficiency due to its significant amounts of iodine. Kelp may induce hyperkalemia in patients with renal insufficiency on a potassium restricted diet.

Advise the patient to consult a health care practitioner prior to taking alfalfa if the patient is taking blood thinners, birth control medication or undergoing hormone replacement therapy (HRT). Advise the patient to consult a health care practitioner prior to taking chlorella, rockweed and kelp if the patient is taking blood thinners.

4.5 Interaction with other medicines and other forms of interaction

Other products affecting THE REAL THING GREEN POWER CAPSULES:

Photosensitizing medicines and photosensitizing herbs may increase medicine-induced photosensitivity when taken in combination with chlorella.

THE REAL THING GREEN POWER CAPSULES affecting other products:

Spirulina may decrease the absorption of iron from food due to its iron-chelating activity.

Spirulina might interfere with immunosuppressive therapy.

Spirulina must be used with caution in combination with other herbs and supplements that might lower blood glucose levels due to its hypoglycaemic effects in patients with diabetes.

Spirulina might affect blood glucose control during surgical procedures. Refer to 4.2 Posology.

Alfalfa and chlorella contain vitamin K that promotes blood clotting, and therefore may reduce the activity and effectiveness of anticoagulants (e.g. warfarin).

Kelp binds strontium and reduces its absorption from the gastrointestinal tract.

4.6 Fertility, pregnancy and lactation

Advise the patient to consult a healthcare practitioner before taking THE REAL THING GREEN POWER CAPSULES during pregnancy and lactation.

Advise patient to avoid use during pregnancy, breastfeeding or if the patient is trying to conceive as safety has not been established. Refer to 4.3 contraindications.

No fertility data is available.

4.7 Effects on ability to drive and use machines

THE REAL THING GREEN POWER CAPSULES has a moderate influence on these abilities due to possible undesirable effects. Use cautiously when driving or operating dangerous machinery as chlorella can cause fatigue.

4.8 Undesirable effects

Overall, idiosyncratic or hypersensitivity reactions may occur. Adverse effects are mainly gastrointestinal. In the case of barley this is due to increased dietary fibre intake.

Blood and lymphatic system disorders

Spirulina can cause mild gum bleeding, mild bruising (rare).

Immune system disorders

Spirulina can cause urticarial rash and pruritis. Barley grass can cause anaphylaxis. Chlorella can cause allergic reactions, including anaphylaxis (rare). Wheat can cause allergic reactions in sensitive individuals.

Endocrine disorders

Alfalfa contains constituents with reported estrogenic activity.

Kelp, due to its iodine content, can affect levels of certain thyroid hormones, and may cause thyroid disorders (hyper- or hypothyroidism) or exacerbate existing hyperthyroidism.

Nervous system disorders

Chlorella can cause fatigue (common). Long term intake of chlorella may cause manganese-induced parkinsonism (rare).

Spirulina may cause fatigue (common), dizziness (common), headache (common).

Respiratory, thoracic and mediastinal disorders

Barley grass can cause chest tightness and rhinoconjunctivitis.

Gastrointestinal disorders

Spirulina may cause nausea (common), vomiting (common), diarrhoea (common), abdominal cramps (common), bloating.

Chlorella can cause gastro-intestinal complaints such as diarrhoea (common), abdominal cramping (common), flatus (common), nausea (common), and green discoloration of faeces due to chlorophyll content (common).

Barley grass can cause flatulence, bloating, abdominal distention and unpleasant taste.

Wheatgrass has been reported to cause nausea, anorexia and constipation.

Abdominal discomfort (common), diarrhoea (common), loose stools, intestinal gas, flatulence during the first week (common), bulkier faeces during the first week, increased faecal volume and increased stool frequency have been reported due to alfalfa.

Rockweed can cause stomach discomfort.

Hepato-biliary disorders

Significant elevation of liver function tests within 2 weeks of starting spirulina supplement.

Skin and subcutaneous disorders

Chlorella can cause photosensitivity reactions (rare).

Barley grass can cause angioedema, urticaria and contact dermatitis.

Alfalfa has been associated with dermatitis.

Kelp may cause or exacerbate acne.

Frequencies of all adverse events are not known.

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

4.9 Overdose

With an overdose, side effects can be precipitated and/or be of increased severity. In the event of an overdosage, advise the patient to stop taking the supplement. Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

THE REAL THING GREEN POWER CAPSULES belongs to category D Complementary Medicine, Health Supplement, class 34.12 Multiple substance formulation.

It is a specifically formulated blend of wheat grass, barley grass and alfalfa leaf powders, and enhanced with spirulina and chlorella, together with 2 different species of nutritional seaweed (rockweed and kelp).

Spirulina is a rich source of nutrients including protein, carbohydrates including glucose polysaccharides, lipids, vitamins (A, E, K, beta-carotene, B-complex) and minerals (iron, manganese, zinc, sodium, potassium, phosphorus, calcium, magnesium, copper, selenium and chromium). It also contains various coloured compounds, including carotenoids, chlorophyll, and phycobiliproteins.

Chlorella is regarded as a health supplement and contains chlorophyll, carotenoids, protein, lipids (omega 3 and 6 fatty acids), carbohydrates, fibre, nucleic acids, vitamins (B12, B6, methyl cobalamine, folate, K), iron, trace elements (zinc, copper, magnesium), minerals and numerous antioxidants such as beta-carotene, ascorbic acid, alpha-tocopherol, zeaxanthin and others. Chlorella contains essential amino acids. Chlorella has antioxidant properties and free radical scavenging activity.

Barley contains 3-11 % beta-glucans, a soluble fibre. Barley contains varying amounts of total tocopherols and tocotrienols, and vitamin E.

Wheatgrass contains large amounts of chlorophyll, and also vitamins (A, C and E), minerals (iron, calcium and magnesium) and amino acids. It may have antioxidant activity and cholesterol lowering effects.

Alfalfa provides vitamins (A, C, E and K), minerals (including manganese) and trace elements. It contains coumestrol (a phytoestrogen) and flavonoids.

Rockweed is high in polysaccharides. The tannins in rockweed are phlorotannins. Rockweed also contains vitamins, and minerals such as iodine. The main fatty acid is oleic acid; it also contains saturated fatty acids, and omega-3 and omega-6 polyunsaturated fatty acids. Rockweed contains essential amino acids. It has antioxidant activity.

Kelp has antioxidant activity. Kelp contains iodine and is a rich source of iron and potassium. It also contains alginates, fucoidan, laminarin and cellulose fibre. Kelp contains essential amino acids.

5.2 Pharmacokinetic properties

Insufficient information is available on spirulina, chlorella, wheatgrass and kelp.

Approximately 17 % of the carbohydrate in barley may not be absorbed by the human body; this may lead to fermentation by microflora in the colon.

Insufficient reliable information is available on alfalfa.

After oral consumption of rockweed extract, its phlorotannins and their metabolites are detectable in plasma within 6 to 24 hours after intake, suggesting that metabolism by gut microbes occur in the large intestine prior to absorption. Phlorotannins are excreted renally within 8 to 24 hours after taking rockweed.

Iodine levels are also increased after taking rockweed powder, although it is not well absorbed. Iodine is excreted in the urine.

Paediatric population

No information is available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The inactive ingredients include –

- magnesium stearate (palm oil)
- vegicap

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

THE REAL THING GREEN POWER CAPSULES have a shelf life of 2 years when stored in a cool dry place at or below 25 °C.

6.4 Special precautions for storage

Protect from light and moisture.

6.5 Nature and contents of container

THE REAL THING GREEN POWER CAPSULES is 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 90 capsules.

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.

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