

# The Real Thing Ecklonia Cava 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 ECKLONIA CAVA CAPSULES contains 400 mg ecklonia cava 13 % extract per capsule.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

THE REAL THING ECKLONIA CAVA CAPSULES contains:

|  | Per capsule | Per 2 capsules |
|--|-------------|----------------|
| <i>Ecklonia cava</i> 13 % extract [leaf] | 400 mg      | 800 mg         |

Inactive ingredients include dextrin, dicalcium phosphate, magnesium stearate (vegetable origin) and vegetable (hypromellose) capsule shells. The capsules are sugar free. For full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

THE REAL THING ECKLONIA CAVA CAPSULES is a clear, hard vegetable capsule shell, size 1, containing a brown powder.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

THE REAL THING ECKLONIA CAVA CAPSULES is a health supplement that has antioxidant activity thereby supporting the body's immune system. This anti-oxidant system acts against free radicals and hence may have a protective effect for the maintenance of good health in humans.

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

### 4.2 Posology and method of administration

Adults 18 years and older: Take 2 (two) capsules orally daily with a glass of water, or as prescribed by the patient's healthcare practitioner.

### Paediatric population

THE REAL THING ECKLONIA CAVA CAPSULES is not suitable for use in children.

### 4.3 Contraindications

- Hypersensitivity to any of the ingredients.

### 4.4 Special warnings and precautions for use

Advise patient to consult a healthcare practitioner if symptoms worsen.

May contain up to 32 microgram iodine per capsule. Hence do not use in a patient with a thyroid problem, except under healthcare practitioner supervision.

### 4.5 Interaction with other medicines and other forms of interaction

None known.

#### **4.6 Fertility, pregnancy and lactation**

Advise patient to consult a healthcare practitioner prior to use if she is pregnant or breastfeeding. Safety in pregnancy and when breastfeeding has not been established. No fertility data is available.

#### **4.7 Effects on ability to drive and use machines**

THE REAL THING ECKLONIA CAVA CAPSULES may have a negligible influence on the ability to drive and use machines.

#### **4.8 Undesirable effects**

##### *Gastrointestinal disorders*

Nausea (less frequent), dyspepsia (less frequent), diarrhoea (less frequent).

##### *Skin and subcutaneous tissue disorders*

Alopecia (less frequent).

##### *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. Healthcare practitioners 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 Certificate of Registration, The Real Thing Food Supplements (Pty) Ltd at telephone 021-701 0244 or e-mail [adr@therealthing.co.za](mailto:adr@therealthing.co.za)

#### **4.9 Overdose**

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

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

THE REAL THING ECKLONIA CAVA CAPSULES belongs to category D Complementary Medicines Health Supplements, class 34.8 Polyphenols (including bioflavonoids).

*Ecklonia cava* is a type of brown algae that contains specific polyphenols called phlorotannins. Polyphenols and phlorotannins have antioxidant effects.

#### **5.2 Pharmacokinetic properties**

Phlorotannins are absorbed after oral ingestion.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

The inactive ingredients include:

- dextrin
- dicalcium phosphate
- magnesium stearate (vegetable origin)
- vegetable (hypromellose) capsule shell

#### **6.2 Incompatibilities**

Not applicable.

**6.3 Shelf life**

THE REAL THING ECKLONIA CAVA CAPSULES has a shelf life of 3 years when stored in a cool, dry place at or below 25 °C.

**6.4 Special storage conditions**

This medicine does not require any special storage conditions.

**6.5 Nature and contents of container**

THE REAL THING ECKLONIA CAVA CAPSULES are packed in a 75 ml amber glass bottle with a child resistant 38 mm polypropylene 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 60 capsules. The bottle is packed in a round core carton fitted with a white insert lid.

Alternatively, it may be packed with a non-child resistant cap fitted with a plastic tamper-evident shrink sleeve.

**6.6 Special precautions for disposal**

No special requirements.

**7 HOLDER OF CERTIFICATE OF REGISTRATION**

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**8 REGISTRATION NUMBER**

(To be allocated)

**9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION**

(To be allocated)

**10 DATE OF REVISION OF THE TEXT**

This is the first edition.

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