

# The Real Thing Anti-X 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 ANTI-X CAPSULES contains Astaxanthin 4 mg per capsule.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

THE REAL THING ANTI-X CAPSULES contain:

*Haematococcus pluvialis* (Astaxanthin 10 % oleoresin) 40 mg

Providing astaxanthin 4 mg

The inactive ingredients in Astaxanthin 10 % oleoresin include safflower oil, sunflower lecithin and mixed tocopherols.

Further inactive ingredients include sunflower seed oil and gelatine (bovine) capsule shell. The capsules are sugar free.

For full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

THE REAL THING ANTI-X CAPSULES is an oval transparent soft-gel capsule, containing a dark brown to red oily liquid.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

THE REAL THING ANTI-X CAPSULES is a health supplement, an extract from *Haematococcus pluvialis* algae that provides a natural source of the carotenoid, astaxanthin. It is a source of antioxidant that protects cells against oxidative damage caused by free radicals.

It is indicated for adults only.

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

### 4.2 Posology and method of administration

Adults over 18 years of age: 2 capsules taken orally daily with a meal and a glass of water. Patients should not exceed the daily dosage level without consulting their healthcare practitioner. Consult a healthcare practitioner for use beyond 3 months.

### Paediatric population

THE REAL THING ANTI-X CAPSULES is not suitable for children.

### 4.3 Contraindications

- If allergic or hypersensitive to *haematococcus pluvialis* algae (astaxanthin) or any of the excipients.

### 4.4 Special warnings and precautions for use

Use cautiously or avoid if the patient has a bleeding disorder.

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

THE REAL THING ANTI-X CAPSULES should be avoided when taking:

- immunosuppressants;
- 5-alpha-reductase inhibitors (medicines with anti-androgen activity).

#### 4.6 Fertility, pregnancy and lactation

Advise the patient to consult a healthcare practitioner prior to use if she is pregnant or breastfeeding. The safety of taking THE REAL THING ANTI-X CAPSULES during pregnancy and lactation is not known. No fertility data is available.

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

THE REAL THING ANTI-X CAPSULES has no or negligible influence on these abilities.

#### 4.8 Undesirable effects

##### *Eye disorders*

Visual changes, advise patients to cease intake immediately.

##### *Gastrointestinal disorders*

Abdominal pain (common), diarrhoea (common), increased bowel movements, red faecal colour (common).

##### *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 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](mailto:adr@therealthing.co.za)

#### 4.9 Overdose

With an overdose, side effects can be precipitated and/or be of increased severity such as severe stomach or abdominal pain. 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 ANTI-X CAPSULES belongs to category D Complementary Medicines, Health Supplements, class 34.4 Carotenoids.

Astaxanthin (*haematococcus pluvialis*) is a carotenoid. Carotenoids are well-known dietary sources of antioxidants that assist the body to fight the oxidative damage caused by free radicals.

Astaxanthin as an antioxidant, contains the highest relative antioxidant activity when compared with alpha-tocopherol, alpha-carotene, beta-carotene, lutein and lycopene.

#### 5.2 Pharmacokinetic properties

Orally astaxanthin is absorbed in the intestines. It is highly lipophilic and has low bioavailability. Absorption may be increased when taken after a meal.

After oral ingestion, astaxanthin is largely distributed to muscle and heart tissue. It can cross the blood-brain barrier, as well as accumulate in the dermis and epidermis.

The elimination half-life of astaxanthin taken orally is from 16 to 52 hours based on a dose variation of 40 mg to 100 mg.

### 6 PHARMACEUTICAL PROPERTIES

#### 6.1 List of excipients

The inactive ingredients include –

- safflower oil (in astaxanthin 10 % oleoresin)
- sunflower lecithin (in astaxanthin 10 % oleoresin)
- mixed tocopherols (in astaxanthin 10 % oleoresin)
- sunflower seed oil
- gelatine (bovine) capsule shell.

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf life**

THE REAL THING ANTI-X CAPSULES has a shelf life of two 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. Protect from heat and moisture.

## **6.5 Nature and content of container**

THE REAL THING ANTI-X CAPSULES 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 capsules in the container. The pack contains 60 capsules. Alternatively, THE REAL THING ANTI-X 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.

## **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**

(To be allocated)

## **10 DATE OF REVISION OF THE TEXT**

This is the first edition.

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