PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

OCUVITE® LUTEIN

Tablets

2. QUALITATIVE AND QUANTIATIVE COMPOSITION

OCUVITE LUTEIN contains	**per tablet**	**per dosage (2 tablets)**
L-ascorbic acid (Vitamin C)	60 mg	120 mg
DL-α-tocopheryl acetate (Vitamin E) (α-TE)	8,8 mg	17,6 mg
Lutein*	**6 mg**	**12 mg**
Zinc (as zinc oxide)	5 mg	10 mg
Zeaxanthin*	**0,5 mg**	**1 mg**
Selenium (as selenium enriched yeast)	20 µg	40 µg

α-TE = α-Tocopherol equivalent

* Encapsulated lutein and zeaxanthin esters from marigold (*Tagetes erecta L.*) flowers

Sugar free

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablets

Light orange, film-coated round biconvex tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

OCUVITE LUTEIN contains antioxidants for the maintenance of eye health. The antioxidants help to protect cells against oxidative damage caused by free radicals.

The ingredients in OCUVITE LUTEIN help to maintain eyesight and support eye health, and:

- may help slow down progression of age-related macular degeneration;
- may help slow down cataract formation;
- improve macular pigment optical density;
- protect the macula from damage caused by light, particularly blue light; and
- contribute to the maintenance of normal vision

4.2 Posology and method of administration

Adults: Take two tablets per day with a meal.

Do not exceed the daily dosage level without consulting a registered healthcare provider.

4.3 Contraindications

- Hypersensitivity to any of the ingredients listed in sections 2 and 6.1.
- Not suitable for children below the age of 18 years.

4.4 Special warnings and precautions for use

OCUVITE LUTEIN should not be used as a substitute for a varied diet. A healthy lifestyle and a balanced diet are essential for staying in good health.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

Pregnant and breastfeeding women should consult a doctor, pharmacist or other healthcare professional before taking this medicine.

4.7 Effects on ability to drive and use machines

OCUVITE LUTEIN is not expected to have a negative effect on the mental or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment or sound coordination and vision.

4.8 Undesirable effects

High doses of vitamins and minerals can have gastrointestinal and other possible side effects. (See section 4.9.)

Reporting of suspected adverse reactions

Reporting suspected adverse reactions 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.

Suspected adverse reactions may also be reported directly to the Applicant using the following e-mail address: PV-SouthAfrica@bausch.com.

4.9 Overdose

Large doses of vitamin C and E may cause diarrhoea, flatulence, abdominal pain and other gastrointestinal disturbances. Vitamin E in large doses have also been reported to cause blurred vision, dizziness, fatigue and weakness. Overdosage of selenium has been associated with loss of hair, nail changes, abdominal pain, nausea, diarrhoea, dermatitis, metallic taste, garlic odour of breath, irritability, fatigue, and peripheral neuropathy. Prolonged use of high doses of zinc may reduce copper levels.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

D 34.12 Multiple substance formulation

Health supplement containing vitamins, minerals and carotenoids. It is a source of antioxidants.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ascorbyl palmitate, ethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, magnesium stearate, maltodextrin, microcrystalline cellulose, mixed tocopherols, modified food starch, polyethylene glycol, red iron oxide (E172), rice starch, silicon dioxide, starch ester, sucrose esters of fatty acids, yellow iron oxide (E172).

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C.

Store in an airtight container, protected from light.

Keep blisters in carton until required for use.

6.5 Nature and contents of container

OCUVITE LUTEIN is provided in 6 x blister packs of 10 tablets each, packed in a printed outer carton.

6.6 Special precautions for disposal and other handling

No special requirements

7. APPLICANT

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Manufactured by

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8. REGISTRATION NUMBER

Not registered

Complementary Medicine: Health Supplement

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

9. DATE OF REVISION OF THE TEXT

September 2022