

# OcuBless<sup>®</sup>

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## 1. Generic Names

- Vitamin C
- Vitamin E
- Lutein
- Zeaxanthin
- Zinc
- Copper

## 2. Qualitative and Quantitative Composition

Vitamin C	.....	250mg
Vitamin E	.....	200IU
Lutein	.....	5mg
Zeaxanthin	.....	1mg
Zinc	.....	40mg
Copper	.....	1mg

## 3. Dosage form and strength

Ocubless is available as Soft gel capsule pack of 5mg Lutein and 1mg Zeaxanthin.

## 4. Clinical particulars

### 4.1 Therapeutic indication

- Ocubless is a dietary supplement to reduce the risk of progression in people with moderate to advanced age-related macular degeneration (AMD).



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- Beta carotene free formula makes it safe for smokers, former smokers and non-smokers.

#### **4.2 Posology and method of administration**

Take 2 soft gel capsule daily; 1 in the morning; 1 in the evening with food or as directed by dietician or healthcare professional.

#### **4.3 Contraindication**

The use of Ocubless is contraindicated in patients with hypersensitivity to any of the ingredients of the formulation.

#### **4.4 Special warnings and precautions for use**

- Do not take this medication with milk, other dairy products, calcium supplements, or antacids that contain calcium. Calcium may make it harder for your body to absorb certain ingredients of the multivitamin.
- Ocubless should not be administered to patient with gallbladder disease or Wilson's disease and bleeding disorders.
- Absorption of lutein from supplementation might decrease in people with cystic fibrosis.

#### **4.5 Drug interactions**

- Warfarin: Increased hypoprothrombinaemia effect occurs with high doses of vitamin E (>400 IU). Vitamin C can reduce the anticoagulant action of warfarin.
- Iron: Iron interferes with the absorption of vitamin E. Absorption of iron increases with coadministration of vitamin C.
- Vitamin C: Acidifies urine resulting in reabsorption of acidic drugs and an increase in the excretion of basic drugs from the renal tubules (unknown clinical relevance).
- Tetracycline and fluoroquinolones: Zinc decreases the absorption of tetracycline and fluoroquinolones.
- Copper: Absorption of copper is decreased by concurrent use of high doses of zinc or vitamin C.

#### **4.6 Use in special population**

- Paediatric: Ocubless has not been studied in children.
- Geriatric: No overall differences in safety or effectiveness have been observed between elderly and other adult patients.
- Liver impairment: Use with caution.
- Renal failure: Use with caution.
- Pregnancy and lactation: Medical advice should be sought before use.

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

Patients should be cautioned against engaging in activities requiring complete mental alertness, and motor coordination such as operating machinery until their response to OCUBLESS is known.

#### **4.8 Undesirable effects**

Nausea ,GI distress, haemorrhagic strokes , CA risk, carotenoderma, choroidal neovascularization, LFTs elevated myocardial infarction, pneumonia, soft drusen formation, stroke can occur.

#### **4.9 Overdose**

Overdose symptoms may include increased thirst or urination, severe nausea or stomach pain, vomiting, bloody diarrhoea, black and tarry stools, hair loss, peeling skin, tingly feeling in or around your mouth, changes in menstrual periods, weight loss, severe headache, severe back pain, blood in your urine, pale skin, easy bruising or bleeding, severe drowsiness, slow heart rate, shallow breathing, weak and rapid pulse, confusion, muscle weakness, cold and clammy skin, blue lips, and seizure (convulsions).

### **5. Pharmacological properties**

#### **5.1 Mechanism of action**

Strategies to prevent the conversion from dry AMD to wet AMD include high-dose consumption of the antioxidant vitamins, C, E, and beta-carotene, plus the minerals zinc and copper.

Lutein and zeaxanthin may also provide risk reduction for AMD

## **5.2 Pharmacodynamic properties**

Not available.

## **5.3 Pharmacokinetic properties**

Not available.

## **6. Nonclinical properties**

### **5.1 Animal Toxicology or Pharmacology**

NA.

## **7. Description**

Ocubless is anti-oxidant vitamin and mineral supplement designed for maintaining macular health. This formula is based on Age Related Eye Disease (AREDS 2) study which is a multi-centric trial conducted in US on 4203 patients.

Zinc was added due to high concentration of it in the RPE. AMD may be linked to zinc deficiency and the loss of zinc dependent coenzymes.

Copper was added to prevent zinc induced copper deficiency.

Lutein and zeaxanthin quench the reactive oxygen species thus giving anti -oxidant property.

The majority of the product is absorbed in the GI tract, with vitamin E requiring fat for its absorption. Zinc absorption may be impacted with food products containing bran or phytates. Components are widely distributed to body tissues. Copper, zinc, lutein and zeaxanthin are excreted primarily in the stool and bile, vitamin C and E in the urine.

## **8. Pharmaceutical particulars**

### **8.1 Incompatibilities**

There are no known incompatibilities.

### **8.2 Shelf-life**

24 months.

### **8.3 Packaging Information**

Ocubless is available as Soft gel capsule pack of 10 capsules.

### **8.4 Storage and handling instructions**

Store in a cool & dry place,

Protect from light and moisture.

Keep out of reach of children.

## **9. Patient Counselling Information**

### **9.1 Adverse Reactions**

Refer part 4.8

### **9.2 Drug Interactions**

Refer part 4.5

### **9.3 Dosage**

Refer part 4.2

### **9.4 Storage**

Refer part 8.4

### **9.5 Risk Factors**

Refer part 4.4

### **9.6 Self-monitoring information**

NA

### **9.7 Information on when to contact a health care provider or seek emergency help**



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Patient is advised to be alert for the emergence or worsening of the adverse reactions and contact the prescribing physician.

### **9.8 Contraindications**

Refer part 4.3

**10. Manufactured by Softgel Healthcare Pvt. Ltd.**

**11. Details of permission or license number with date**

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