

## MarineOmega

# PROFESSIONAL INFORMATION - MARINE OMEGA SCHEDULING STATUS: **SO**

## COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

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

### 1. NAME OF THE MEDICINE

**MARINE OMEGA**. Soft gelatine capsules. Sugar free
Derived from seafood

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

## **Qualitative and Quantitative declaration:**

Fish oil	1 100 mg
Providing:	
Eicosapentaenoic acid (EPA)	165 mg
Docosahexaenoic acid (DHA)	110 mg
Total Omega 3 fatty acids	330 mg
Euphausia superba (Krill) [oil]	50 mg
Providing:	
Eicosapentaenoic acid (EPA)	6 mg
Docosahexaenoic acid (DHA)	2,75 mg
Total Omega 3 fatty acids	11 mg

#### 3. PHARMACEUTICAL FORM

**MARINE OMEGA** soft gelatine capsules are amber to red viscous liquid in clear, oblong-shape soft gelatine

capsule, 22 mm length with cloudy to bright red phospholipid or astaxanthin particles.

#### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

#### MARINE OMEGA:

- Is a source of omega-3 fatty acids, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) for the maintenance of good health.
- Helps maintain cardiovascular health.
- Helps support cognitive health and/or brain function.
- Helps to reduce serum triglycerides.

## 4.2 Posology and method of administration:

## Posology:

Take two (2) soft gelatine capsules with 250 ml of liquid with your morning and evening meals.

**Paediatric population:** Not recommended for children under the age of 18 years.

#### 4.3 Contraindications

Hypersensitivity (allergy) to seafood or any of the ingredients, including excipients of **MARINE OMEGA**. (See section 6.1).

## 4.4 Special warnings and precautions for use

Consult a healthcare professional prior to use:

- If you are pregnant or breastfeeding.
- If you have a medical condition or are taking prescription medication.

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

No known interactions.

## 4.6 Fertility, pregnancy and lactation

Consult a health care practitioner prior to use if you are

pregnant or breastfeeding your baby.

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

**MARINE OMEGA** should have no or negligible influence on the ability to drive and use machines.

#### 4.8 Undesirable effects

No known side-effects.

Should your general health worsen or if you experience any untoward effects while taking **MARINE OMEGA**, please consult your doctor, pharmacist or other healthcare professional for advice.

### 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

#### 4.9 Overdose

None known. Treatment is supportive and symptomatic.

### 5. PHARMACOLOGICAL PROPERTIES

## Pharmacological classification

D 34.6 Fats, Oils and Fatty acids

### 5.1 Pharmacodynamic properties

Not applicable.

## 5.2 Pharmacokinetic properties

Not applicable

## 5.3 Preclinical safety data

Not applicable.

#### 6. PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Gelatine, glycerine, tocopherol-rich extract, vanillin.

### 6.2 Incompatibilities

Not applicable.

#### 6.3 Shelf life

24 months.

### 6.4 Special precautions for storage

- Store at or below 25 °C.
- Protect from moisture and light.
- Do not refrigerate.
- Keep in the original container until ready for use.

#### 6.5 Nature and contents of container

**MARINE OMEGA** soft gelatine capsules are amber to red viscous liquid in clear, oblong-shape soft gelatine capsule, 22 mm length with cloudy to bright red phospholipid or astaxanthin particles.

120 soft gelatine capsules are packed in 300 ml white round HDPE plastic bottles with white polypropylene caps.

## 6.6 Special precautions for disposal and other handling

No special requirements.

## 7. HOLDER OF CERTIFICATE OF REGISTRATION

Nu Skin South Africa, 22 Magwa Crescent, Waterfall City, Ground and 1st Floor, Midrand 1682, South Africa.

#### 8. REGISTRATION NUMBER

Will be allocated by the Authority upon registration.

## DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION

November 2023