PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

VegOmega•3

COMPLEMENTARY MEDICINE

Health Supplement

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority for its quality, safety or intended use.

Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS
S0

1 NAME OF THE MEDICINE
A.VOGEL VEGOMEGA•3 (capsules)

2 QUALITIVE AND QUANTITIVE COMPOSITION

Each capsule contains:
Linum usitatissimum (Flaxseed oil) .....400 mg
providing alpha-linolenic acid (ALA) .....200 mg
Schizochytrium senso lato oil (DHA algae oil) .....214 mg
providing
docosahexaenoic acid (DHA) .....75 mg
eicosapentaenoic acid (EPA) .....1,9 mg

Sugar free

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Yellowish oval soft gel capsules.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
A.VOGEL VEGOMEGA•3 capsules are a vegan source of the omega-3 essential fatty acids, docosahexaenoic acid (DHA), alpha-linolenic acid (ALA) and eicosapentaenoic acid (EPA), that are essential for the maintenance of good health and must be included in the diet as the body does not produce them.

DHA contributes to the maintenance of normal brain function and normal vision. DHA maternal intake contributes to the normal development of the eyes of the foetus and breastfed infants.

DHA and EPA helps support/maintain (normal) heart/cardiovascular health/function.

DHA and EPA helps support the development of the brain, eyes and nerves in children.

A.VOGEL VEGOMEGA•3 capsules are non-GMO and gluten free.

4.2 Posology and method of administration

Posology

Adults and adolescents 12 years and older:
For the maintenance of good health:
Take 1 capsule daily.

For the maintenance of normal vision, brain and cardiovascular health/function:
Take 4 capsules daily.

Pregnancy and breastfeeding:
(Contributes to normal development of the eyes of the foetus and breastfed infants)
Take 4 capsules daily.

Special populations

Elderly population:
No dosage adjustment is required for this population.

Paediatric population
Children 2 – 12 years:
For the maintenance of good health:
Take 1 capsule daily.

To support brain, eye and nerve development:
Take 2 capsules daily.

Method of administration
For oral use only.
Take capsules with water, chew or squeeze the contents of the capsule over food.

4.3 Contraindications
- Do not use in cases of known hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use
- A.VOGEL VEGOMEGA•3 should be used with caution and under medical supervision in patients using anticoagulants and antiplatelet drugs (see section 4.5).

4.5 Interaction with other medicines and other forms of interaction
- A.VOGEL VEGOMEGA•3 may increase the bleeding time in patients receiving anticoagulant and antiplatelet therapy, including, but not limited to, aspirin, warfarin and clopidogrel (see section 4.4).

4.6 Fertility, pregnancy and lactation
Women of childbearing potential/Contraception in males and females
No information available.

Pregnancy
During pregnancy all medicines should be taken under the supervision of a health practitioner.

Breastfeeding
During lactation all medicines should be taken under the supervision of a health practitioner.

Fertility
No effect on fertility expected.

4.7 Effects on ability to drive and use machines
A.VOGEL VEGOMEGA•3 has no or negligible influence on mental and/or physical abilities to perform or execute tasks or activities requiring mental alertness, judgment and/or sound coordination and vision.

4.8 Undesirable effects

Adverse reactions are grouped into the following frequency classifications:

Very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1 000 to < 1/100), rare (≥ 1/10 000 to < 1/1 000), very rare (< 1/10 000), not known (cannot be assessed from the available data).

Tabulated list of adverse reactions

Body System	**Undesirable effect** (Frequency not known)
Gastrointestinal disorders:	Nausea and vomiting

a. Paediatric population
Frequency, type and severity of adverse reactions in children are expected to be the same as in adults.

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 professionals are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form"**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

4.9 Overdose
In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).
Treatment of overdosage should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
D34.6 Fats, Oils and Fatty Acids
Pharmacotherapeutic group and ATC code:
Omega-3-triglycerides including other esters and acids/C10AX06
Mechanism of action:
No information available.

5.2 Pharmacokinetic properties
No information available.

5.3 Preclinical safety data
No information available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Peppermint oil, natural
RRR-alpha-tocopherol, natural

Capsule shell:
Carrageenan
Glycerol
Modified pea starch
Water

Sugar free

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months.
After opening: use within 2 months.

6.4 Special precautions for storage
Store at or below 25 °C in a cool, dry place.
Store in the original package.
Protect from light.
Do not use if security seal is broken.

6.5 Nature and contents of container
Amber glass bottles with aluminium pilfer proof screw caps.

Pack size: 30 capsules.

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product
No special requirements.

7 THE HOLDER OF THE CERTIFICATE OF REGISTRATION
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8 REGISTRATION NUMBER(S)
Listing number: 150116

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
To be allocated.

10 DATE OF REVISION OF TEXT
August 2020

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