

PROFESSIONAL INFORMATION FOR
MEDICINES FOR HUMAN USE



VegOmega-3

COMPLEMENTARY MEDICINE

Health Supplement

This unregistered medicine has not been evaluated by the SAHPRA for its safety, quality 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 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Linum usitatissimum (Flaxeed oil)..... 400 mg
providing Alpha-Linolenic acid (ALA)..... 200 mg
Schizochytrium algae oil..... 214 mg
providing Docosahexaenoic acid (DHA).....75 mg
Not derived from fish or other animal sources.

Capsule shell contains sugar:

Glycerol and Sorbitol..... 86 mg

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 fatty acids docosahexaenoic acid (DHA) and alpha-linolenic acid (ALA) that are essential for the maintenance of good health and must be included in the diet as the body does not produce them. ALA and DHA help maintain normal blood cholesterol levels and normal blood triglyceride levels. DHA plays a role in visual development and normal eye function. DHA is a building block of the brain and helps with the transmission of messages between nerves. DHA supports cognitive function and mental balance in early life.

4.2 Posology and method of administration

Posology

Adults and adolescents 12 years and older:

Maintenance of good health: 1 - 2 capsules daily

To support brain and eye function: 3 - 4 capsules daily

Maintenance of normal blood cholesterol and blood triglyceride levels:

3 - 4 capsules daily

Take capsules with water or squeeze the contents over food.

Special populations

Paediatric population

Children 5 - 11 years:

Maintenance of good health: 1 capsule daily

To support brain and eye function: 2 capsules daily

Children 2 - 4 years: 1 capsule daily

Take capsules with water or squeeze the contents over food

Method of administration

For oral use.

4.3 Contraindications

• Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Consult your healthcare provider if you take medication to:

• Reduce clotting (known as blood thinners or anti-coagulants) (see section 4.5 Interaction with other medicines and other forms of Interaction).

A.Vogel VegOmega-3 should be used with caution in diabetes:

• The capsule shell contains sorbitol which may affect blood sugar levels.
• The contents can be squeezed out of the capsule shell.

Sorbitol Warning:

Patients with the rare hereditary condition of sorbitol intolerance should not take A.Vogel VegOmega-3 capsules, as the capsule shell contains sorbitol.

However, the contents can be squeezed out of the capsule shell if patients have a sorbitol intolerance.

4.5 Interaction with other medicines and other forms of interaction

• A.Vogel VegOmega-3 may increase the effects of blood thinning medication, including, but not limited to, aspirin, warfarin and clopidogrel.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential/Contraception in males and females

No information available.

Pregnancy

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

Breastfeeding

During pregnancy and 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 the effect of 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

May cause gastro-intestinal disturbances, e.g. nausea and vomiting. The frequency is unknown.

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 the 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 (section 4.8 Undesirable effects).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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
RRR-alpha-tocopherol
Capsule shell:
Eucheuma seaweed
Monoglycerides of fatty acids
Potato starch
Capsule shell contains sugar:
Glycerol and Sorbitol..... 86 mg

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 containing 30 capsules with aluminium pilfer proof screw cap.

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

January 2020

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