

PROFESSIONAL INFORMATION**PHYTOPURE® KRILL OIL**

Complementary Medicine: Health Supplement

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

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

PHYTOPURE® KRILL OIL, 590 mg, Capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Krill oil	590 mg
-----------	--------

Providing:

Omega-3 fatty acids	159 mg
---------------------	--------

of which EPA (Eicosapentaenoic acid)	89 mg
--------------------------------------	-------

and DHA (Docosahexaenoic acid)	41 mg
--------------------------------	-------

Phospholipids	330 mg
---------------	--------

Choline	41, 3 mg
---------	----------

Contains astaxanthin 50 µg (antioxidant).

Contains sorbitol (26 mg per capsule).

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Capsules.

Clear, soft (bovine) gelatine capsules filled with a dark red, viscous oil with characteristic odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

PHYTOPURE KRILL OIL is a health supplement that contains krill oil extracted from Antarctic krill, *Euphausia superba*. It is a source of omega-3 fatty acids for the maintenance of good health, including cardiovascular health, and helps to support liver function.

4.2 Posology and method of administration

Posology

Adults 18 years and older

Take 2 capsules per day with or without food.

Users should be advised not to exceed the recommended maximum dose of 2 capsules per day.

PHYTOPURE KRILL OIL can be used for up to 6 months. For use beyond 6 months, monitor patients for safety and tolerability.

Paediatric population

Adolescents and children under 18 years of age

PHYTOPURE KRILL OIL is not recommended for adolescents and children under 18 years.

Method of administration

For oral use only.

4.3 Contraindications

- Hypersensitivity to krill oil, omega-3 fatty acids, shellfish, or any of the other components of the formulation (see Section 2 *Qualitative and Quantitative Composition* and Section 6.1 *List of excipients*).

4.4 Special warnings and precautions for use

PHYTOPURE KRILL OIL is sourced from crustacean shellfish. Individuals with known shellfish hypersensitivity should not take PHYTOPURE KRILL OIL (see Section 4.3 *Contraindications*). Hypersensitivity has been known to occur with shellfish and should it develop, use should be discontinued.

High doses of DHA and EPA might decrease coagulation and increase the risk of bleeding due to antiplatelet effects. Advise users with a bleeding disorder or those taking anticoagulants or antiplatelet medicines to consult a healthcare provider prior to use. They must also adhere to the recommended maximum daily dosage of two capsules (see Section 4.2 *Posology and method of administration* and Section 4.5 *Interaction with other medicines and other forms of interaction*).

Due to the possible anticoagulant effects, patients scheduled for elective surgery should discontinue PHYTOPURE KRILL OIL two weeks before such surgical procedures.

4.5 Interaction with other medicines and other forms of interaction

Interaction with medicines

ANTICOAGULANTS/ANTIPLATELET MEDICATION

PHYTOPURE KRILL OIL in combination with anticoagulants and/or antiplatelet medicines may increase the risk of bleeding (see Section 4.4 *Special warnings and precautions for use*). Advise patients who are using anticoagulants or antiplatelet agents to strictly adhere to the dosage instructions. Such patients should stop taking PHYTOPURE KRILL OIL if they develop bruising, nose bleeds, excessive bleeding from minor injuries, or bleeding from the gums and report to their healthcare provider.

ANTIDIABETIC MEDICINES

PHYTOPURE KRILL OIL in combination with antidiabetic medicines may increase the risk of hypoglycaemia. Patients taking antidiabetic medicines should carefully monitor blood glucose levels when supplementation with PHYTOPURE KRILL OIL is initiated or discontinued. It may be necessary to adjust the dosage of their antidiabetic medication.

Interaction with herbs and supplements

HERBS AND SUPPLEMENTS WITH ANTICOAGULANT/ANTIPLATELET PROPERTIES

PHYTOPURE KRILL OIL should be used with caution in combination with herbs and supplements that may have anticoagulant properties in medicinal amounts due to a possible increased risk of bleeding (see Section 4.4 *Special warnings and precautions for use*). Advise patients who are using anticoagulants or antiplatelet agents to strictly adhere to the dosage instructions. Examples of such herbs and supplements include angelica, clove, danshen, garlic, ginger, ginkgo, and Panax ginseng.

HERBS AND SUPPLEMENTS WITH HYPOGLYCAEMIC POTENTIAL

Caution is required when PHYTOPURE KRILL OIL is combined with herbs or supplements with hypoglycaemic potential due to possible additive effects (see Section 4.4 *Special warnings and precautions for use*). Examples of such herbs and supplements include alpha-lipoic acid, berberine, bitter melon, chromium, fenugreek, garlic, ginger, horsetail, Panax ginseng, and many others.

4.6 Fertility, pregnancy, and lactation

Pregnancy and lactation

There is insufficient reliable information regarding the use of PHYTOPURE KRILL OIL during pregnancy. Avoid using PHYTOPURE KRILL OIL during pregnancy and lactation.

Fertility

The effects of PHYTOPURE KRILL OIL on human male and female fertility are not known.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed. Given its side-effect profile, it is unlikely that PHYTOPURE KRILL OIL will influence the ability to drive or use machinery. Users should be advised to determine how PHYTOPURE KRILL OIL affects them before they engage in these activities.

4.8 Undesirable effects

a) Summary of safety profile

Krill oil seems to be well tolerated when taken orally in doses up to 4 grams daily. Most common adverse effects are bloating, decreased appetite, diarrhoea, flatulence, heartburn, nausea, and stomach discomfort.

b) Tabulated list of adverse events

Below is a summary of the side effects of krill oil:

Immune system disorders

Frequency unknown: Hypersensitivity reactions

(* Cannot be estimated from available data)

Gastrointestinal disorders

Frequency unknown: Abdominal discomfort or upset, decreased appetite, taste change, heartburn, bloating, flatulence, diarrhoea, and nausea

Skin and subcutaneous tissue disorders

Frequency unknown: Facial skin oiliness or localised pimples

Reporting of suspected adverse reactions

Reporting suspected adverse reactions is important. It allows continued monitoring of the benefit/risk balance of PHYTOPURE KRILL OIL. Healthcare 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>

In addition, adverse events can also be reported to Coyne Healthcare (Pty) Ltd via their website (www.coyne-healthcare.com) or telephonically [+27 (0)21 421 9144].

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see *Section 4.8 Undesirable effects*). Supportive and symptomatic treatment should be provided as appropriate.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

D34.6 Complementary Medicines: Health Supplements: Fats, Oils and Fatty Acids

5.2 Pharmacokinetic properties

Absorption

There is preliminary clinical research to suggest that there is a greater increase in plasma levels of EPA and DHA following supplementation with krill oil compared to fish oil.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Bovine gelatine (capsules)

Ethyl vanillin

Glycerol

Sorbitol (26 mg per capsule)

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two years

6.4 Special precautions for storage

Store at or below 25 °C in an airtight container. Protect from light.

Keep in the outer carton until required for use. Keep the bottle tightly closed.

Do not use after the expiry date stated on the bottle and carton.

6.5 Nature and contents of container

Clear, soft, (bovine) gelatine capsules filled with a dark red, viscous oil with characteristic odour packed in a white, opaque, glass bottle with a metal, non-child-resistant, screw-on cap with a tamper-evident seal and silica gel desiccant inside an outer carton.

Pack size: 60 capsules

6.6 Special precautions for disposal

PHYTOPURE KRILL OIL should not be disposed of in drains or sewerage systems.

Advise patients to return all unused medicines to their pharmacist for disposal.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Coyne Healthcare (Pty) Ltd

Moorings 1

Portswood Ridge

Portswood Road

V&A Waterfront

Cape Town

8. REGISTRATION NUMBER

To be allocated by the Authority upon registration.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be allocated.

10. DATE OF REVISION OF THE TEXT

First compiled July 2022.