

PROFESSIONAL INFORMATION

Category D: human complementary medicine. This medicine has not been evaluated by the SAHPRA. This medicine is not intended to diagnose, treat, cure or prevent any disease.

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

Obel Omega capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients per serving (2 capsules): Fish Oil (2000 mg), EPA (360 mg), DHA (240 mg), Vitamin E (7 mg).

3. PHARMACEUTICAL FORM

Obel Omega capsules are soft gel capsules.

4. CLINICAL PARTICULARS

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4.1. Therapeutic Indications

Obel Omega capsules are used for supplementation.

4.2. Posology and method of administration

Posology

Adults: The usual dose is 2 capsules once a day.

Method of administration

Obel Omega capsules should be taken once a day with or without food.

4.3. Contraindications

Avoid if allergic or sensitive to any of the listed ingredients. Do not exceed recommended dosage(s).

4.4. Special warnings and precautions for use

Obel Omega capsules must not be used if hypersensitive (allergic) to any ingredients. Obel Omega capsules should not be used in people who are taking blood thinning medications.

4.5. Interaction with other medicines and other forms of interaction

Obel Omega capsules known to react with any other blood thinning medicines. If you are taking prescription medication, consult a healthcare practitioner prior to use. Obel Omega capsules are not known to react badly with any types of food or drink.

4.6. Fertility, pregnancy and lactation

Obel Omega capsules should not be used during pregnancy and a healthcare provider should be consulted for advice prior to taking Obel Omega capsules when breastfeeding.

4.7. Effects on ability to drive and use machines.

No effects on the ability to drive and use machines has been reported.

4.8. Undesirable effects

None known. Should general health worsen, or if any untoward effects are experienced while using this product, please consult a doctor, pharmacist, or other health care professional for advice.

4.9. Overdose

If you take more Obel Omega Capsules than you should:

If anyone, especially a child, accidentally takes too much Obel Omega Capsules contact your doctor or local poison centre immediately. If symptoms persist consult your doctor. If you see a doctor or have to go to hospital for any reason, tell them what medicines you are taking.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

34.6 Fatty Acids. Obel Omega capsules contains fish oil as supplementation to the diet.

5.2. Pharmacokinetic properties

There is no pharmacokinetic data available on the active ingredients via the route of administration described.

5.3. Preclinical safety data

There is no preclinical safety data available on the active ingredients via the route of administration described.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Inactive ingredients: gelatin, glycerin and water.

6.2. Incompatibilities: None

6.3. Shelf life

2 years

6.4. Special precautions for storage

Store below 30 °C in a cool, dry place. Store out of reach of children. Do not use after the expiry date stated on the bottle. The expiry date refers to the last day of the month.

6.5. Nature and contents of container

Obel Omega Capsules are soft gelatin capsules with oil inside in a black HDPE tamper-evident container, containing 120 capsules.

Special precautions for disposal

No special requirements.

7. PROPOSED HOLDER OF CERTIFICATE OF REGISTRATION

Galileo Labs Ltd.

5630 Venice Blvd #1119, LA, CA 90019.

3rd Floor, 14505 Bannister Road SE,

Calgary, AB, T2X 3J3.

Name and Address of Holder of Certificate of Registration

Microbel Laboratories (Pty) Ltd,

86 Gazelle Ave, Corporate Park South,

Midrand, Gauteng, 1685, South Africa.

Email: info@microbel.co.za

+27 11 076 4000

8. REGISTRATION NUMBER(S)

Application Number: TBC by SAHPRA

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

TBA by SAHPRA. Date of Revision: April 2025