

## PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS:** S0

**PROPRIETARY NAME (AND DOSAGE FORM):**

Obel Omega Capsules

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

**Category D: Complementary Medicine**, D34.6 Fatty Acids

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

**Read this leaflet carefully as it contains important information for you.**

Obel Omega Capsules are available without a doctor's prescription for supplementation. Nevertheless, you still need to use Obel Omega Capsules carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Obel Omega Capsules with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must consult a doctor if your condition worsens or does not improve after 7 days.

**What is in this leaflet:**

- 1. What Obel Omega Capsules are and what it is used for**
- 2. What you need to know before you use Obel Omega Capsules**
- 3. How to use Obel Omega Capsules**
- 4. Possible side effects**
- 5. How to store Obel Omega Capsules**
- 6. Contents of the pack and other information**

**1. WHAT OBEL OMEGA CAPSULES ARE AND WHAT THEY ARE USED FOR**

Obel Omega Capsules are used for supplementation. This product may be used by adults aged 18 years and over.

**2. WHAT YOU NEED TO KNOW BEFORE YOU USE OBEL OMEGA CAPSULES**

- Do not take if using blood thinning medications.
- Do not use Obel Omega Capsules if you are hypersensitive (allergic) to any ingredients.

- If you are unsure if you should use Obel Omega Capsules, talk to your doctor or pharmacist.

**Warnings and precautions:**

Do not take if using blood thinning medications.

Obel Omega Capsules are for ingestion only.

If you are taking prescription medication, consult a healthcare practitioner prior to use. If any unwanted/adverse effect develops, discontinue use and consult your doctor or pharmacist. Use is described in adults aged 18 years and older.

**Tell your healthcare provide prior to use**

- If you are taking any prescription medication especially blood thinning medications
- If you are pregnant, trying to become pregnant or are breast-feeding ask your doctor or pharmacist for advice

**Pregnancy and Breastfeeding**

Obel Omega Capsules should only be used during pregnancy if a healthcare provider is be consulted for advice as well as prior to taking Obel Omega Capsules when breastfeeding.

### **Driving and using machines**

Obel Omega Capsules has no known effect on an individual's ability to drive or operate machinery.

### **Taking other medicines or food and drink with Obel Omega Capsules**

Always tell your healthcare provider if you are taking any other medicine. Obel Omega Capsules is not known to react badly with any types of food or drink.

## **3. HOW TO USE OBEL OMEGA CAPSULES**

### **The usual dose is:**

#### **Adults:**

Take 2 capsules per day.

### **Method of administration:**

Obel Omega Capsules are for ingestion only.

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.

### **If you forget to take a dose of Obel Omega Capsules:**

Do not take a double dose to make up for forgotten individual doses.

#### **4. POSSIBLE SIDE EFFECTS**

None known. If any side effects are experienced, please tell your doctor or pharmacist.

Obel Omega Capsules is not known to react badly with any other medicines or any types of food or drink.

Should your general health worsen, or if you experience any untoward effects while using this product, please consult your doctor, pharmacist, or other health care professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist. You can also report side effects 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>. By reporting side effects, you can help provide more information on the safety of Obel Omega Capsules.

#### **5. HOW TO STORE OBEL OMEGA CAPSULES**

Store below 30 °C in a cool, dry place. Store out of reach of children. Store out of reach of children. Store in the original package / container. Do not store in a bathroom. Do not use after the expiry date printed on the bottle. The expiry date refers to the last day of that month. Do not use Obel Omega Capsules if you notice visible signs of deterioration. Return all unused medicine to your

pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets). Shelf life: 2 years

## **6. CONTENTS OF THE PACK AND OTHER INFORMATION**

**What Obel Omega Capsules contains:**

**Each serving (2 capsules) contains:**

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

Inactive ingredients: gelatin, glycerin and water.

**What Obel Omega Capsules looks like and contents of the pack:**

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

**Distributed by:**

Galileo Labs Ltd.

5630 Venice Blvd #1119, LA, CA 90019.

3rd Floor, 14505 Bannister Road SE,

Calgary, AB, T2X 3J3.

customercare@obellabs.co.za

**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

**This leaflet was last revised**

25 March 2025

**Registration/Application number**

Application Number: TBC

Access to the corresponding Professional Information (PI): [www.obellabs.co.za](http://www.obellabs.co.za)

## PASIËNTINLIGTINGSPAMFLET

**SKEDULERINGSSTATUS:** S0

### **EIENDOMSNAAM (STERKTE EN DOSEERVORM)**

Obel Omega Kapsules

Aktiewe bestanddele per porsie: Visolie (20000 mg), EPA (360mg), DHA (240 mg), Vitamien E (7 mg).

**Kategorie D: Komplementêre Medisyne.** D 34.6 Vetsure

Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer ten opsigte van kwaliteit, veiligheid of voorgenome gebruik nie.

**Lees dié hele pamflet aandagtig deur, dit bevat belangrike inligting.**

**OBEL OMEGA KAPSULES** is beskikbaar sonder 'n voorskrif van die dokter, vir aanvulling. Nietemin, **OBEL OMEGA KAPSULES** moet nogtans versigtig gebruik word om die beste resultate te verkry.

- Moenie hierdie pamflet weggooi nie. U mag dit moontlik weer moet lees.
- Moenie **OBEL OMEGA KAPSULES** met enige ander person deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of advies benodig.
- Besoek 'n dokter as u simptome vererger of nie na 7 dae verbeter nie.

### **WAT IS IN HIERDIE PAMFLET**

1. Wat **OBEL OMEGA KAPSULES** is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u **OBEL OMEGA KAPSULES** gebruik.
3. Hoe om **OBEL OMEGA KAPSULES** te gebruik.
4. Moontlike newe-effekte.
5. Bergingsaanwysings vir **OBEL OMEGA KAPSULES**.
6. Inhoud van die verpakking en ander inligting.

### **1. WAT OBEL OMEGA KAPSULES IS EN WAARVOOR DIT GEBRUIK WORD:**

**OBEL OMEGA KAPSULES** word gebruik vir aanvulling. Hierdie produk kan deur volwassenes van 18 jaar en ouer gebruik word.

### **2. WAT U MOET WEET VOORDAT OBEL OMEGA GEBRUIK WORD:**

- Moet nie neem as bloedverdunnende medikasie gebruik word nie.

- Moenie **OBEL OMEGA KAPSULES** gebruik indien u hipersensitief (allergies) is vir enige bestandele.
- Indien u onseker is om Obel Omega Kapsules te gebruik, konsulteer u gesondheidsorgverskaffer of apteker.

### **WAARSKUWINGS EN VOORSORGMAATREËLS:**

Moet nie neem as bloedverdunnende medikasie gebruik word nie.

Moenie Obel Omega Kapsules gebruik as hy hipersensitief (allergies) is vir enige bestanddele nie.

As u voorskifmedikasie neem, raadpleeg 'n gesondheidsorgpraktisyn voor gebruik. As enige ongewenste / nadelike effek ontwikkel, staak die gebruik en raadpeeg jou dokter of apteker. Gebruik word beskryf in volassenes van 18 jaar en ouer.

### **Vertel jou gesondheidsorg voor gebruik**

- As jy enige voorskifmedikasie neem, veral bloedverdunnende medikasie
- As jy swanger is, probeer om swanger te raak of borsvoed, vra jou dokter of apteker vir raad.

### **Swangerskap en borsvoeding**

Obel Omega Kapsules moet nie tydens swangerskap gebruik word nie en 'n gesondheidsorgverskaffer moet geraadpeeg word vir advies voordat Obel Omega Kapsules geneem word tydens borsvoeding.

### **Bestuur en gebruik van masjinerie**

Obel Omega Kapsules het geen bekende effek op 'n individu se vermoë om te bestuur of masjinerie te bestuur nie.

Neem ander medisyne of kos en drank saam met Obel Omega Kapsules

Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medikasie neem. Dit is nie bekend dat Obel Omega Kapsules sleg reageer met enige soorte kos of drank nie, maar kan die opname van voedingstowwe en medikasie beïnvloed.

### **3. HOE OM OBEL OMEGA KAPSULES TE GEBRUIK**

**Die gewone dosis is:**

**Volwassenes:**

Neem 2 kapsules per dag.

**Metode van toediening:**

Obel Omega Kapsules is slegs vir inname.

**As jy meer Obel Omega Kapsules neem as wat jy moet:**

As iemand, veral 'n kind per ongeluk te veel Obel Omega Kapsules neem, kontak jou dokter of plaaslike gifsentrum onmiddellik. Obel Omega Kapsules moet nie langer as een week aaneenlopend gebruik word nie. As simptome voortduur, raadpeel jou dokter. As jy 'n dokter sien of om een of ander rede hopsitaal toe moet gaan, vertel hulle watter medisyne jy neem.

As jy vergeet om 'n dosis Obel Omega Kapsules te neem:

Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

**4. MOONTLIKE NEWE-EFFEKTE:**

Niks bekend nie. As enige newe-effekte ervaar word, vertel asseblief jou dokter of apteker.

Dit is nie bekend dat Obel Omega Kapsules sleg reageer met enige ander medisyne of enige soorte kos of drank nie.

As jou algemene gesondheid vererger, of as jy enige ongewenste effekte ervaar terwyl jy hierdie produk gebruik, raadpleeg asseblief jou dokter, apteker of ander gesondheidswerker vir advies. As jy enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief jou dokter of apteker in kennis. Jy kan ook newe-effekte aan SAHPRA rapporteer via die 6.04 "Adverse Drug Reaction

Reporting Form”, wat aanlyn gevind word onder SAHPRA se publikasies: <https://www.sahpra.order.za/Publications/Index/8>. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van Obel Omega Kapsules te verskaf.

## **5. BERGINGSAAANWYSINGS VIR OBEL OMEGA KAPSULES**

Bewaar in 'n koel, droeë plek, teen of benede 30 °C. Bêre buite bereik van kinders. Berg in die oorspronklike verpakking. Moet nie in 'n badkamer bêre nie. Moet dit nie gebruik na die vervaldatum wat op die bottles gedruk is nie. Die vervaldatum verwys na die laaste dag van daardie maand. Moenie Obel Omega Kapsules gebruik as jy sigbare tekens van agteruitgang opmerk nie. Stuur alle ongebruikte medisyne terug na jou apteker. Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie. Raklewe: 2 jaar.

## **6. INHOUD VAN DIE VERPAKKING EN ANDER INLIGTING**

### **WAT OBEL OMEGA KAPSULES BEVAT**

#### **Elke porsie (2 kapsules) bevat:**

Aktiewe bestanddele: Visolie (2000 mg), EPA (360 mg), DHA (240 mg), Vitamien E (7 mg).

Onaktiewe bestanddele: Gelatien, gliserien en water.

**Voorkoms van Obel Omega Kapsules en inhoud van die verpakking:**

Obel Omega Kapsules is 'n sagte gelatienkapsule met olie binne in 'n swart HDPE-peuterhouer, wat 120 kapsules bevat.

**Versprei deur:**

Galileo Labs Ltd

5630 Venice Blvd #1119, LA, CA 90019.

3<sup>rd</sup> Floor, 14505 Bannister Road SE,

Calgary, AB, T2X 3J3.

[customercare@obellabs.co.za](mailto:customercare@obellabs.co.za)

**Naam en adres van houer van registrasiesertifikaat**

Microbel Laboratories (Pty) Ltd

86 Gazelle Avenue, Corporate Park South,

Midrand, Gauteng, 1685, South Africa.

Email: [info@microbel.co.za](mailto:info@microbel.co.za)

+27 11 076 4000

**Datum van laaste hersiening**

25 Maart 2025

**Registrasie/Aansoeknommer:**

TBA.

**Toegang tot ooreenstemmende Professionele Inligting (PI): [www.obellabs.co.za](http://www.obellabs.co.za)**