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

S0

1. NAME OF THE MEDICINE

Swissgarde Omega capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients per serving (1 capsule): Fish Oil (1000 mg), EPA (180 mg), DHA (120 mg), Vitamin E (3.5 mg).

3. PHARMACEUTICAL FORM

Swissgarde Omega capsules are soft gel capsules.

4. CLINICAL PARTICULARS

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.

4.1. Therapeutic Indications

Swissgarde Omega capsules are used for supplementation.

4.2. Posology and method of administration

Posology

Adults: The usual dose is 1 capsule per day.

Method of administration

Swissgarde 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

Swissgarde Omega capsules must not be used if hypersensitive (allergic) to any ingredients. Swissgarde 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

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

4.6. Fertility, pregnancy and lactation

Swissgarde Omega capsules should not be used during pregnancy and a healthcare provider should be consulted for advice prior to taking Swissgarde 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 Swissgarde Omega Capsules than you should:

If anyone, especially a child, accidentally takes too much Swissgarde 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. Swissgarde 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

Swissgarde Omega Capsules are soft gelatin capsules with oil inside in a black HDPE tamper-evident container, containing 30 capsules.

Special precautions for disposal

No special requirements.

7. PROPOSED HOLDER OF CERTIFICATE OF REGISTRATION

Sportron Group (Pty) Ltd

Route 21 Business Park, 59 Regency Drive, Centurion, South Africa, 0157.

Tel: +27 (11) 317 8500

www.sportron.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

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

PROFESSIONELE INLIGTING

Kategorie D: Menslike komplementêre medisyne. Hierdie medisyne is nog nie deur SAHPRA geëvalueer nie. Die doel van hierdie medisyne is nie om enige siekte te diagnoseer, behandel, genees of te voorkom nie.

SKEDULERINGSTATUS

S0

1. NAAM VAN MEDIKASIE

Swissgarde Omega kapsules

2. KWALITATIEWE EN KWANTITATIEWE SAMESTELLING

Aktiewe bestanddele per porsie (een kapsule): Visolie (1000 mg), EPA (180 mg), DHA (120 mg), Vitamien E (3.5 mg).

3. FARMASEUTIESE DOSEERVORM

Swissgarde Omega kapsules is sagte GEL kapsules

4. KLINIESE BESONDERHEDE

Kategorie D: Menslike komplementêre medisyne. Hierdie medisyne is nog nie deur SAHPRA geëvalueer nie. Die doel van hierdie medisyne is nie om enige siekte te diagnoseer, behandel, genees of te voorkom nie.

4.1 Terapeutiese Indikasies

Swissgarde Omega kapsules word gebruik vir aanvulling.

4.2 Dosering En Metode Van Toediening

Dosering

Volwassenes: Die gewonde dosis is daagliks 1 kapsule.

Metode van toediening

Swissgarde Omega kapsules moet een keer per dag geneem word met of sonder voedsel.

4.3 Kontra-indikasies

Vermy as allergies of sensitief vir enige van die genoemde bestanddele. Moenie die aanbevole dosis(se) oorskry nie.

4.4 Waarskuwings en spesiale voorsorgmaatreëls

Swissgarde Omega kapsules moet nie gebruik word as u hipersensitief (allergies) is vir enige bestanddele nie. Swissgarde Omega Kapsules moet nie gebruik word by mense wat bloed verdunnende medikasie neem nie.

4.5 Interaksies met ander medisyne en ander tipe interaksies

Swissgarde Omega kapsules wat bekend is om met enige ander bloed verdunnende medisyne te reageer. As jy voorskrif medikasie neem, raadpleeg ‘n gesondheidsorgpraktisyn voor gebruik. Dit is nie bekend dat Swissgarde Omega kapsules sleg reageer met enige tipe kos of drank nie.

4.6 Vrugbaarheid, swangerskap en borsvoeding

Swissgarde Omega kapsules moet nie tydens swangerskap gebruik word nie en ‘n gesondheidsorgverskaffer moet geraadpleeg word vir advies voordat Swissgarde Pro biotiese en Pre biotiese kapsules geneem word tydens borsvoeding.

4.7 Effek op die vermoë om te bestuur en masjinerie te gebruik

Geen effekte op die vermoë om te bestuur of om masjinerie te gebruik is aangemeld nie

4.8 Newe-effekte

Geen bekend. Indien u algemene gesondheid versleg, of indien u enige newe-effekte ervaar tydens die gebruik van hierdie produk, moet jou dokter, apteker of ander gesondheidsorgverskaffer vir advies geraadpleeg word.

4.9 Oordosering

As hy meer Swissgarde Omega kapsules neem as wat jy moet:

As iemand, veral ‘n kind per ongeluk te veel Swissgarde Omega kapsules neem, kontak jou dokter of plaaslike gif sentrum onmiddellik. As simptome voortduur, raadpleeg jou dokter. As jy ‘n dokter sien of om een of ander rede hospitaal toe moet gaan, vertel hulle watter medisyne jy neem.

5. FARMAKOLOGIESE EIENSKAPPE

5.1 Farmakodinamiese eienskappe

34.6 Vetsure. Swissgarde Omega kapsules bevat visolie as aanvulling op die dieet.

5.2 Farmakokinetiese eienskappe

Daar is geen farmakokinetiese data beskikbaar oor die aktiewe bestanddele via die toedienings roete wat beskryf word nie.

5.3 Pre-kliniese gesondheidsdata

Daar is geen pre kliniese veiligheids data beskikbaar oor die aktiewe bestanddele via die toedienings roete wat beskryf word nie.

6 FARMASEUTIESE BESONDERHEDE

6.1 Lys van hulpstowwe

Onaktiewe bestanddele: Gelatien, gliserien en water.

6.2 Onverenigbaarhede

Geen.

6.3 Rakleeftyd

2 Jaar.

6.4 Spesiale voorsorgmaatreëls vir bewaring

Bewaar benede 30 °C in ‘n koel droë plek. Hou buite bereik van kinders. Moet nie die produk na die vervaldatum aangedui op die houer gebruik nie. Die vervaldatum verwys na die laaste dag van die maand.

6.5 Samestelling en inhoud van die houer

Swissgarde Omega kapsules is sagte gelatienkapsule met olie binne in ‘n swart HDPE-peuter houer, wat 30 kapsules gevat.

Spesiale voorsorgmaatreëls vir wegdoening

Geen spesiale vereistes nie.

7. VOORGESTELDE HOUER VAN REGISTRASIESERTIFIKAAT

Sportron Group (Pty) Ltd

Route 21 Business Park, 59 Regency Drive, Centurion, South Africa, 0157.

Tel: +27 (11) 317 8500

www.sportron.co.za

Naam en Adres van Houer van Registrasiesertifikaat

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. REGISTRASIENOMMER(S)

Aansoek nommer: TBC deur SAHPRA

9. DATUM VAN EERSTE GOEDKEURING/HERNUWING VAN GOEDKEURING

TBA deur SAHPRA. Datum van hersiening: April 2025.