

Professional information for MI-VITAMIN® OMEGA-3

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

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

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE: MI-VITAMIN® OMEGA-3 soft capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION: Each soft capsule contains:

MEG-3® 1812TG Oil	1000 mg
Fish oil	998,7 mg:
<i>eicosapentaenoic acid (EPA)</i>	180 mg
<i>docosahexaenoic acid (DHA)</i>	120 mg
Mixed tocopherols (antioxidant)	1,3 mg
Sugar free	

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oblong, uncoloured, translucent soft capsules containing a clear yellow oil.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

MI-VITAMIN® OMEGA-3 is a source of omega-3 fatty acids for the maintenance of good health. Helps support normal heart and brain function.

4.2 Posology and method of administration

Adults and children over 6 years: Take 1 – 3 capsules per day with meals or as recommended by your healthcare provider.

4.3 Contraindications

Hypersensitivity to any of the active ingredients, including the excipients of MI-VITAMIN® OMEGA-3 (see sections 2 and 6.1).

4.4 Special warnings and precautions for use

None known.

4.5 Interaction with other medicines and other forms of interaction

No known interactions.

4.6 Fertility, pregnancy and lactation

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking MI-VITAMIN® OMEGA-3.

4.7 Effects on ability to drive and use machines

MI-VITAMIN® OMEGA-3 has no effect on the ability to drive a vehicle and use machines.

4.8 Undesirable effects

None known.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of MI-VITAMIN® OMEGA-3 is important. It allows continued monitoring of the benefit/risk balance of MI-VITAMIN® OMEGA-3. Health care professionals are asked to report any suspected adverse reactions via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <http://www.sahpra.org.za/Publications/Index/8>

4.9 Overdose

No known symptoms of over dosage have been established. If suspected overdose occurs, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: D34.6 Fats, Oils and Fatty Acids

OMEGA-3 fatty acids are essential fatty acids that help with the maintenance of good health.

Docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA) help to support normal heart and brain function.

5.2 Pharmacokinetic properties

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatine capsule (containing bovine gelatine and glycerine).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C. Store in airtight container, protected from light.

6.5 Nature and contents of container

White HDPE tubs with white HDPE lids with a silver induction seal in the lid, containing a Patient Information Leaflet.

Pack size: 90 soft capsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

LeBasi Pharmaceuticals (Pty) Ltd.

San Domenico Unit 6

10 Church Street

Durbanville, Cape Town 7551

Marketed by:

At Life Products South Africa (Pty) Ltd.

Bryanston Ridge Office Park, Block B

13A Bruton Road

Corner Main & Bruton Roads

Bryanston, Gauteng, South Africa

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF TEXT

Will be allocated by SAHPRA upon registration.