



Professional Information for OMEGA-3 with VITAMIN D₃

COMPLEMENTARY MEDICINE: HEALTH SUPPLEMENT

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

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

MANNATECH OMEGA-3 WITH VITAMIN D₃ CAPSULES

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Fish oil concentrate	1 050 mg
providing Omega-3 fatty acids	555 mg
[containing eicosapentaenoic acid (EPA)	330 mg
and docosahexaenoic acid (DHA)	225 mg
Cholecalciferol (Vitamin D ₃)	4,1 µg

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Soft capsule.

Pale-yellow, lightly pliable, clear, soft gel capsule.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

MANNATECH OMEGA-3 with VITAMIN D₃ is a health supplement which provides essential omega-3 fatty acids and vitamin D₃ for the maintenance of good health. Omega-3 with Vitamin D₃ helps maintain and support cardiovascular health and brain health and function. It also helps in the absorption and use of calcium and phosphorous.

4.2 Posology and method of administration

Take 2 capsules daily with a glass of water or other liquid.
Do not exceed the recommended dosage.

4.3 Contraindications

Hypersensitivity to fish oil, omega-3 fatty acids, EPA, DHA, vitamin D₃ or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Patients should consult a relevant health care provider before use if they suffer from a bleeding disorder, take blood thinning medicines (see section 4.5) or are asthmatic with sensitivity to aspirin.

The use of vitamin D supplements such as MANNATECH OMEGA-3 with VITAMIN D₃ may worsen hypercalcaemia.

4.5 Interaction with other medicines and other forms of interaction

Anticoagulant or antiplatelet medicines:

MANNATECH OMEGA-3 with VITAMIN D₃ may potentiate the effects of anticoagulant and antiplatelet medicines or herbal supplements with blood thinning effects (see section 4.4).

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

MANNATECH OMEGA-3 with VITAMIN D₃ is unlikely to affect the ability to drive and use machines.

4.8 Undesirable effects

MANNATECH OMEGA-3 with VITAMIN D₃ is generally well-tolerated.

General disorders and administration site conditions:

Frequency unknown: burping with fishy aftertaste.

Reporting suspected adverse reactions

Reporting suspected adverse reactions after authorisation of MANNATECH OMEGA-3 with VITAMIN D₃ is important. It allows continued monitoring of the benefit/risk balance of MANNATECH OMEGA-3 with VITAMIN D₃. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity. See section 4.8.

In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: D 34.12 Health supplement: Multiple substance formulation.

Mechanism of action:

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 maintain/support cardiovascular health.

Vitamin D₃ is a fat-soluble vitamin that plays a role in cardiovascular health.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatine,
Glycerine (E422),
Orange flavour.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C, in a dry place.

Keep the bottle tightly closed.

Do not use if inner seal is missing or broken.

6.5 Nature and contents of container

HDPE round bottle with a cap PP cap containing 60 capsules.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

LeBasi Pharmaceuticals (Pty) Ltd
San Domenico Building, Ground Floor, Unit 6
10 Church Street
Durbanville, 7551

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

March 2021.