

**PROPRIETARY NAME AND DOSAGE FORM:****OMEGA 369 SOFTGEL CAPSULES (30)**

**DISCLAIMER:** This medicine has not been evaluated by SAHPRA for its quality, safety or intended use. This medicine is not intended to diagnose, treat, cure, or prevent any disease.

**SCHEDULING STATUS:** Unscheduled

**COMPOSITION:** Each softgel contains:

Ingredients	Elemental value	*NRV
Omega 3-6-9 fatty acids from Flaxseed oil (Linaceae - Linum usitatissimum L.)	1000 mg	-
<b>Total fatty acid profile:</b>		
Total Omega-3 fatty acids comprising of alpha-linolenic acid (ALA)	550 mg	-
Total Omega-6 fatty acids comprising of linoleic acid	150 mg	-
Total Omega-9 fatty acids comprising of oleic acid	150 mg	

\* South African Nutrient reference values for individuals 4 years and older  
- Not established

**Other Ingredients:** Gelatine (bovine), glycerine & purified water.

**HALAL CERTIFIED AT SOURCE****PHARMACOLOGICAL CLASSIFICATION:**

34.6 Category D (Health Supplement) [SO]

**PHARMACOLOGICAL ACTION:** Health supplement.

**INDICATIONS:** Indicated as a supplement where poor dietary intake of the listed active ingredients exist.

**CONTRA-INDICATIONS:**

- Hypersensitivity to any of the ingredients.

**WARNINGS AND SPECIAL PRECAUTIONS:**

- Large doses may give rise to gastrointestinal discomfort.

**INTERACTIONS:**

No known interactions with existing conditions at recommended dose.

Medicines that could interact with Omega 369 are:

- Anti-coagulant medications (e.g., warfarin): Potential for increased bleeding risk.
- Blood pressure medications: Omega-3 fatty acids might lower blood pressure, requiring monitoring.
- Diabetes medications: Omega-3 fatty acids could affect blood sugar levels.
- Anti-platelet drugs (e.g., aspirin): Increased risk of bleeding.
- Cholesterol-lowering medications: Omega-3 fatty acids may enhance their effects.

**DOSAGE AND DIRECTIONS FOR USE:**

The recommended usage is:

- Adults take 1 softgel daily with meals.

Do not exceed the recommended dose. This product should not be used as a substitute for a balanced diet.

**SIDE EFFECTS AND SPECIAL PRECAUTIONS:**

This supplement should be used with caution in individuals with the following medical conditions:

- Allergic to seafood, fish or shellfish
- Allergic to soy
- Diabetes
- Heart disease or conditions
- Pancreas disorder
- Thyroid problems
- a lung disease that makes it harder to breathe (chronic obstructive pulmonary disease or COPD),
- high triglycerides (a type of fat): Omega-6 fatty acids can raise triglyceride levels. Do not use omega-6 fatty acids if your triglycerides are too high.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

In case of an accidental overdose, discontinue use and seek medical professional assistance immediately. Treatment is symptomatic and supportive.

Symptoms overdose may include:

- Nausea and/or diarrhoea.

**IDENTIFICATION:**

Clear softgel capsule with yellow oil inside.

**PRESENTATION:**

Packaged as a printed box with tamperproof seal, labelled with clear, detailed information printed on the box.

Contents are 3 blister packs of 10 capsules each, containing 30 capsules in total.

**STORAGE INSTRUCTIONS:**

Store in a cool, dry place below 25 °C. Do not leave container open.

**KEEP OUT OF REACH OF CHILDREN.****REGISTRATION NUMBER:**

To be allocated.

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

Vitotech

Physical address: Cnr Parkin & Delson Street  
North End, Gqeberha, 6001, South Africa.

Tel: 041 816 3100

Email: [ask@vitatechhealth.com](mailto:ask@vitatechhealth.com)

Website: [www.vitatechhealth.com](http://www.vitatechhealth.com)

**DATE OF PUBLICATION OF THE PACKAGE INSERT:**

July 2023

**vitotech® NAPPI CODE:**

**3001502001**

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**HANDELSNAAM EN DOSERINGSVORM:****OMEGA 369 SOFTGEL CAPSULES (30)**

**VRYWARING:** Hierdie medisyne is nie deur SAHPRA geëvalueer ten opsigte van die kwaliteit, veiligheid of beoogde gebruik daarvan nie. Hierdie medisyne is nie bedoel vir die diagnostering, behandeling, genesing of voorkoming van enige siekte nie.

**SKEDULERINGSTATUS:** Ongeskeduleerd

**SAMESTELLING:** Elke softgel bevat:

Bestanddele	Elementeel waarde	*NRV
Omega 3-6-9 vetsure van Lijnsaadolie (Linaceae - Linum usitatissimum L.)	1000 mg	-

**Total fatty acid profile:**

Totale Omega-3-vetsure bestaande uit alfa-linoleensuur (ALA)	550 mg	-
Totale Omega-6-vetsure bestaande uit linoleensuur	150 mg	-
Totale Omega-9-vetsure bestaande uit oliensuur	150 mg	

\* Suid Afrikaanse Voedings verwysingswaardes vir persone 4 jaar en ouer  
- Nie vasgestel nie

**Ander bestanddele is:** Gelatien (bees), glicerien & gesuiwerde water.

**HALAL GESERTIFISEER BY DIE BRON.****FARMAKOLOGIESE KLASIFIKASIE:**

34.6 Kategorie D (Gesondheidsaanvuller) [SO]

**FARMAKOLOGIESE WERKING:** Gesondheidsaanvuller

**INDIKASIES:** Aangedui as 'n aanvulling waar swak dieetintname van die genoemde aktiewe bestanddele voorkom.

**KONTRA-LINDIKASIES:**

- Hipersensitiviteit vir enige van die bestanddele.

**WAASKUWINGS EN SPESIALE VOORSORGMAATREËLS:**

- Groot dosisse mag lei tot maag-darmongemak.

**INTERAKSIES:**

Geen bekende interaksies teen die aanbevolle dosis.

Middels wat met Omega 369 kan interakteer is:

- Middels vir bloedverdunning (byvoorbeeld warfarin): Moontlike verhoogde bloedingrisiko.
- Middels vir bloeddruk: Omega-3 vetsure kan moontlik bloeddruk verlaag, wat monitering vereis.
- Diabetes medikasie: Omega-3 vetsure kan bloedsuikervlakke beïnvloed.
- Anti-platelet medisyne (byvoorbeeld aspirien): Verhoogde risiko van bloeding.
- Cholesterolverlagende medisyne: Omega-3 vetsure kan hul effekte versterk.

**DOSIS EN GEBRUIKSAANWYSINGS:**

Die aanbevolle gebruik is:

- Volwassenes neem daagliks 1 softgel saam met etes. Moenie die aanbevolle dosis oorskry nie. Die produk moet nie 'n gebalanseerde dieet vervang nie.

**MOONTLIKE NEWE-EFFEKTE EN SPESIALE VOORBERGING:**  
Hierdie aanvulling moet met versigtigheid gebruik word by individue met die volgende mediese toestande:

- Allergies vir seekos, vis of skulpe
- Allergies vir soja
- Diabetes
- Hart siekte of toestande
- Pancreas wanorde
- Skildklier probleme
- 'n Longsiekte wat dit moeilik maak om asem te haal (chronic obstructive pulmonary disease of COPD),
- Hoë triglyceriede ('n tipe vet): Omega-6 vetsure kan triglyceriedvlakke verhoog. Moet nie omega-6 vetsure gebruik as jou triglyceriede te hoog is nie.

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDEN VAN DIE BEHANDELING DAARVAN**

In geval van 'n toevalige oordosis, staak die gebruik en soek onmiddellik mediese hulp. Behandeling is simptomaties en ondersteunend.

Simptome van 'n oordosis kan insluit:

- naarheid, en/of diarree

**IDENTIFIKASIE:**

Deurskynde softgel met geel olie binne-in.

**AANBIEDING:**

Verpak as 'n gedrukte boks met 'n verseelde sertifikaat, gemerk met duidelike, gedetailleerde inligting wat op die boks gedruk is. Die inhoud bestaan uit 3 blaaspakke met elk 10 kapsules wat 'n totaal van 30 kapsules bevat.

**BERGINGSAAWYSINGS:**

Bere op 'n koel, droë plek onder 25 °C. Moenie die houer oop laat.

**HOU BUITE BEREIK VAN KINDERS****REGISTRASIE NOMMER:**

Word ge-allokeer.

**NAAM EN BESIGHEIDS ADRES VAN DIE APPLIKANT:**

Vitotech

Address: Cnr Parkin & Delson Street

North End, Gqeberha, 6001, Suid Afrika.

Tel: 041 816 3100

E-pos: [ask@vitatechhealth.com](mailto:ask@vitatechhealth.com)

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**DATUM VAN PUBLIKASIE VAN HIERDIE PASIËNT INLIGTING PAMFLET:**

Julie 2023

**vitotech® NAPPI CODE:**

**3001502001**

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## PROPRIETARY NAME AND DOSAGE FORM:

**OMEGA 369 SOFTGEL CAPSULES (30)**

**DISCLAIMER:** This medicine has not been evaluated by SAPHRA. This medicine is not intended to diagnose, treat, cure, or prevent any disease.

Read all this leaflet carefully because it contains important information for you. This medicine is available without a doctor's prescription, for you to use as a vitamin supplement.

Nevertheless, you still need to use it carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must go see a doctor if you experience worrying symptoms.

**SCHEDULING STATUS:** Unscheduled**CONTAINS:** Each softgel contains:

Ingredients	Elemental value	*NRV
Omega 3-6-9 fatty acids from Flaxseed oil (Linaceae - Linum usitatissimum L.)	1000 mg	-
<b>Total fatty acid profile:</b>		
Total Omega-3 fatty acids comprising of alpha-linolenic acid (ALA)	550 mg	-
Total Omega-6 fatty acids comprising of linoleenic acid	150 mg	-
Total Omega-9 fatty acids comprising of oleic acid	150 mg	

\* South African Nutrient reference values for individuals 4 years and older  
- Not established

**Other Ingredients:** Gelatine (bovine), glycerine & purified water.

**HALAL CERTIFIED AT SOURCE****WHAT IS THIS SUPPLEMENT USED FOR:**

Omega 369 softgel capsules supports:

- Cardiovascular function and lowers the levels of harmful cholesterol.
- Cognitive health by providing essential fatty acids that are crucial for brain function.
- Reducing inflammation, benefits joint health. It can alleviate joint pain and stiffness, promoting mobility and comfort.
- Supports skin health helping to maintain skin moisture and elasticity, reducing the appearance of wrinkles.
- A robust immune system and enhances the body's ability to defend against infections and illnesses.
- Balancing cholesterol levels, promoting overall well-being. It can help reduce bad cholesterol while maintaining good cholesterol levels in the body.

**BEFORE YOU TAKE THIS SUPPLEMENT:**

Do not take if you are allergic to any of the ingredients.

Take special care when taking any supplement:

- Do not exceed the daily recommended amount.

- Seek professional advice if suffering from any **allergies**.
- Seek professional advice if **any other medications** are being taken or another medical condition is present.
- If you are taking other supplements, read the label as these supplements may contain the same ingredients.
- If you are **pregnant or breast feeding** your baby, please consult your health care provider for advice before taking this medicine.
- This supplement should not impair or affect your ability to **drive or operate heavy machinery**.

**TAKING/USING OTHER MEDICATION:**

There are no known interactions at the recommended dosage for healthy individuals. See "PACKAGE INSERT Interactions."

**HOW TO TAKE:**

The recommended usage is:

- Adults take 1 softgel daily with meals.

**IF YOU TAKE MORE THAN YOU SHOULD:**

In the event of an overdose, consult your doctor or pharmacist immediately. If neither is available, contact that nearest hospital or medical centre. Treatment is symptomatic and supportive.

**POSSIBLE SIDE EFFECTS:**

These supplements are generally well-tolerated when taken as directed. Symptoms of overdose may include:

- Nausea and/or diarrhoea.

If you experience any unusual or severe side effects, discontinue use, and seek medical attention.

**IDENTIFICATION:**

Clear softgel capsule with yellow oil inside.

**PRESENTATION:**

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**VRYWARING:** Hierdie medisyne is nie deur SAPHRA geëvalueer nie. Hierdie medisyne is nie bedoel om enige siekte te diagnostiseer, behandel, genees of voorkom nie.

Lees alle inligting in die inligtingsblad noukeurig, dit bevat belangrike inligting vir die verbruiker. Die medisyne is beskikbaar sonder 'n dokters voorskrif, vir gebruik as 'n vitamien aanvulling. Nieteenstaande, dit is belangrik dat die produk korrek gebruik moet word om die beste resultate te verkry.

- Moenie die pamphlet weggooi nie, dit mag dalk nodig wees om dit weer te lees
- Vra jou apteker indien jy meer inligting of advies nodig het
- Besoek die dokter indien daar kommerwekkende simptome is.

**SKEDULERINGSTATUS:** Ongeskeduleerd**SAMESTELLING:** Elke softgel bevat:

Bestanddele	Elementale waarde	*NRV
Omega 3-6-9 vetsure van Lijnsaadolie (Linaceae - Linum usitatissimum L.)	1000 mg	-
<b>Total fatty acid profile:</b>		
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\* Suid Afrikaanse Voedings verwysingswaardes vir persone 4 jaar en ouer  
- Nie vasgestel nie

**Ander bestanddele is:** Gelatien (bees), gliserien & gesuiwerde water.

**HALAL GESERTIFISEER BY DIE BRON.****WAARVOOR WORD HIERDIE AANVULLING GEBRUIK:**

Omega 369 softgel capsules ondersteun:

- Kardiovaskuläre funksie en verlaag die vlakke van skadelike cholesterol.
- Kognitiewe gesondheid deur essensiële vetsure te verskaf wat noodsaaklik is vir breinfunksie.
- Die vermindering van inflammasie, voordele vir gewrigsgesondheid. Dit kan gewrigspyn en styfheid verlig, mobiele en gemak bevorder.
- Ondersteun die gesondheid van die vel deur die handhawing van vel-moisture en elastisiteit, en verminder die voorkoms van rimpels.
- 'N Robuste immuunstelsel en verbeter die liggaam se vermoë om teen infeksies en siektes te verdedig.
- Die balans van cholesterolvlakte, wat algemene welstand bevorder. Dit kan slegte cholesterol verminder terwyl dit goeie cholesterolvlakte in die liggaam handhaaf.

**VOORDAT JY HIERDIE AANVULLING NEEM:**

Moenie dit inneem as jy allergies is vir enige van die bestanddele nie.

Wees versigtig wanneer jy enige aanvulling gebruik:

- Moet nie die daaglike aanbevolle hoeveelheid oorskry nie.
- Raadpleeg 'n professionele persoon as jy aan enige **allergie** ly.
- Raadpleeg 'n professionele persoon as enige **ander medikasie** gebruik word of 'n ander mediese toestand teenwoordig is.
- As jy ander aanvullings gebruik, lees die etiket aangesien hierdie aanvullings dieselfde bestanddele kan bevat.
- As jy **swanger is of jou baba borsvoed**, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne gebruik.
- Hierdie aanvulling behoort nie jou vermoë om te **bestuur of swaar masjinerie** te bedryf nie, te benadeel of te

**INTERAKSIES MET ANDER MEDISYNE:**

Daar is geen bekende interaksies by die aanbevolle dosis vir gesonde individue nie. Verwys na die « VOUBILJET interaksies »

**HOE OM DIT TE GEBRUIK:**

Die aanbevolle gebruik is:

- Volwassenes neem daagliks 1 softgel saam met etes.

**AS JY MEER NEEM AS WAT JY MOET:**

In geval van 'n oordosis, raadpleeg onmiddellik jou dokter of apteker. As hulle nie beskikbaar is nie, kontak die naaste hospitaal of mediese sentrum. Behandeling is simptomaties en ondersteunend.

**MOONTLIK NEWE-EFFEKTE:**

Hierdie aanvullings word gewoonlik goed verdra as dit soos voorgeskryf geneem word. Simptome van 'n oordosis kan insluit:

- naarrheid, en/of diarree

**IDENTIFIKASIE:**

Deurskynde softgel met geel olie binne-in.

**AANBIEDING:**

Verpak as 'n gedrukte boks met 'n verseëerde sertificaat, gemerk met duidelike, gedetailleerde inligting wat op die boks gedruk is. Die inhoud bestaan uit 3 blaaspakke met elk 10 kapsules wat 'n totaal van 30 kapsules bevat.

**BERGINGSAAWYSINGS:**

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**REGISTRASIE NOMMER:**

Word ge-allokeer.

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