12853 FRONT
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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

NUTRILITE™ OMEGA-3 COMPLEX - soft gelatin capsules

Each soft gelatin capsule contains:

Engraulis ringens **(Peruvian anchovy), *Sardinops sagax* (South African sardine) and *Scomba scobrus* (Mackerel) oil providing**	**1030 mg**
Eicosapentaenoic acid	**180 mg**
Docosahexaenoic acid	**120 mg**
Total Omega 3 fatty acids	**380 mg**
Vitamin E (d-alpha tocopherol)	**5 mg a-TE**
Sugar free	

Each soft gelatin capsule contains glycerol 131 mg.

D.34.12 Multiple substance formulation
COMPLEMENTARY MEDICINE – HEALTH SUPPLEMENT

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

Read all of this leaflet carefully because it contains important information for you.

NUTRILITE™ OMEGA-3 COMPLEX is available without a doctor's prescription for you, to help support your heart and brain health. Nevertheless, you still need to use NUTRILITE™ OMEGA-3 COMPLEX carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NUTRILITE™ OMEGA-3 COMPLEX with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice See section 4.

What is in this leaflet:

1. What NUTRILITE™ OMEGA-3 COMPLEX is and what it is used for
2. What you need to know before you take NUTRILITE™ OMEGA-3 COMPLEX
3. How to take NUTRILITE™ OMEGA-3 COMPLEX
4. Possible side effects
5. How to store NUTRILITE™ OMEGA-3 COMPLEX
6. Contents of the pack and other information

1. What NUTRILITE™ OMEGA-3 COMPLEX is and what it is used

NUTRILITE™ OMEGA-3 COMPLEX contains concentrated omega 3 polyunsaturated fatty acids fish oil which provides eicosapentaenoic acid and docosahexaenoic acid in a 3:2 ratio.

Polyunsaturated Omega 3 fatty acids are not manufactured in the body and must come from your diet. NUTRILITE™ Omega-3 Complex offers a convenient way to add the essential fatty acids to your diet. Omega 3 fatty acids support and helps maintain healthy heart and brain function.

The beneficial effect for maintenance of normal brain function is obtained with a daily intake of 250 mg of docosahexaenoic acid (DHA).

The beneficial effect for support and maintenance of heart health is obtained with a daily intake of 250 mg of the combination of Eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA).

"A varied diet is the most effective and safe way to achieve good nutrition, health, body composition as well as mental and physical performance."

2. What you need to know before you take NUTRILITE™ OMEGA-3 COMPLEX

Do Not Take NUTRILITE™ OMEGA-3 COMPLEX

- If you are hypersensitive (allergic) to any of the ingredients (Listed in section 6.0)

If any of the above applies to you, do not take this medicine, and consult your relevant health care provider.

Warnings and precautions

Take special care with Nutrilite™ Omega-3 Complex. Consult a relevant health care provider prior to use:

- If you are due to have or have had surgery recently.
- If you have had a trauma recently.
- If you have a kidney problem.
- If you have diabetes which is not controlled.
- If you have problems with your liver. Your doctor will monitor any effects NUTRILITE™ OMEGA-3 COMPLEX may have on your liver with blood tests.
- If you are pregnant, planning to become pregnant or are breastfeeding.
- If you are allergic to fish and soya.
- If you suffer from a bleeding disorder.
- If you take blood thinners.
- If you are asthmatic with sensitivity to aspirin.

Do not exceed daily dosage level without consulting a relevant healthcare provider.

Consult a relevant healthcare provider for use beyond 6 months.

Children and Adolescents

Nutrilite™ Omega-3 Complex is not recommended for children under 18 years of age.

Other medicines and NUTRILITE™ OMEGA-3 COMPLEX

If you are taking blood thinners, such as warfarin, you may need extra blood tests and your usual dose of your blood thinning medicine may have to be changed.

Always tell your healthcare provider if you are taking any other medicines including all complementary or traditional medicines.

Pregnancy and breast-feeding

If you are pregnant particularly in the first three months, planning to become pregnant or are breast-feeding, please consult your doctor or pharmacist or relevant healthcare provider before taking NUTRILITE™ OMEGA-3 COMPLEX.

Safety of NUTRILITE™ OMEGA-3 COMPLEX in pregnancy and breastfeeding has not established.

Driving and using machines

NUTRILITE™ OMEGA-3 COMPLEX is not expected to influence your ability to drive. However, you should not drive, use machinery or perform tasks that require concentration until you are certain that NUTRILITE™ OMEGA-3 COMPLEX does not adversely affect your ability to do so safely (See Possible side-effects).

Important Information about some of the ingredients of NUTRILITE™ OMEGA-3 COMPLEX

NUTRILITE™ OMEGA-3 COMPLEX is derived from seafood and contains soya-bean oil. If you are allergic to fish or soya, do not use this health supplement. NUTRILITE™ OMEGA-3 COMPLEX Contains glycerol and may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told that you have an intolerance to some sugars, you should not take NUTRILITE™ OMEGA-3 COMPLEX.

3. How to take NUTRILITE™ OMEGA-3 COMPLEX

Always take NUTRILITE™ OMEGA-3 COMPLEX exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The usual dose for Adults is: Take one capsule three times a day, with a meal or as directed by your healthcare provider. Do not exceed the recommended daily dose unless directed by your doctor.

If you take more NUTRILITE™ OMEGA-3 COMPLEX than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take NUTRILITE™ OMEGA-3 COMPLEX

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

4. Possible Side Effects

NUTRILITE™ OMEGA-3 COMPLEX can have side effects.

Not all side effects reported for NUTRILITE™ OMEGA-3 COMPLEX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NUTRILITE™ OMEGA-3 COMPLEX, please consult your doctor, pharmacist or healthcare provider for advice. Some less frequent side effects of NUTRILITE™ OMEGA-3 COMPLEX can be serious. If any of the following happen to you, stop taking NUTRILITE™ OMEGA-3 COMPLEX and tell your doctor immediately or go to the casualty department at your nearest hospital as you will need immediate medical attention or hospitalization:

Common side effects (occur in 1 to 10 users in 100):
Stomach problems like abdominal distension, pain, constipation, diarrhea, indigestion (dyspepsia), gas, belching (eructation), acid reflux, feeling sick (nausea) and being sick (vomiting).

Uncommon side effects (occur in 1 to 10 users in 1,000):

- high blood sugar levels.
- gout.
- dizziness.
- problems with taste.
- headache.
- low blood pressure
- nose bleeds.
- blood in your stools.
- rash.

Rare side effects (occur in 1 to 10 users in 10,000):

- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not allergic reactions.
- raised red skin rash (hives or urticaria).
- liver disorders, with possible changes in the results of certain blood tests.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of Side Effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under:

SAHPRA's publications: SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", https://www.sahpra.org.za/Publications/Index/8.

Botswana's s publications: BOMRA via Suspected Adverse Drug Reactions Reporting Form, https://www.bomra.co.bw/index.php/suspected-adverse-drug-reactions-reporting-form Namibia's publication: Adverse Medicine Reaction (Safety Yellow Form) https://nmrc.gov.na/documents/81630/410067/Safety+Yellow+Form.pdf/8cbbf343-3cf8-dba3-7ec1-50b881fdab26.

May also report to Amway South Africa Pty Limited using the following email: Regulatory_Department@Amway.com.

By reporting side effects, you can help provide more information on the safety of NUTRILITE™ OMEGA-3 COMPLEX.

5. How to store NUTRILITE™ OMEGA-3 COMPLEX

Store out of the reach and sight of children.

Store in the original package/ container. Keep the container tightly closed to protect from light, heat and moisture.

Do not store above 25°C. Do not use NUTRILITE™ OMEGA-3 COMPLEX after the expiry date stated on the label.

The expiry date refers to the last day of that month. Do not use NUTRILITE™ OMEGA-3 COMPLEX, if you notice the capsules have changed shape or colour.

Disposal of NUTRILITE™ OMEGA-3 COMPLEX

Return all unused medicines to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NUTRILITE™ OMEGA-3 COMPLEX contains

The active substances are omega 3-fatty acids, eicosapentaenoic acid (EPA) docosahexaenoic acid (DHA) and vitamin E (as d-alpha tocopherol).

The other ingredients are bovine gelatin, glycerol, soybean oil and water.

What NUTRILITE™ OMEGA-3 COMPLEX look like and contents of the pack

Clear soft gelatin capsules containing pale yellow oil.

It is available in white HD polyethylene container with lift 'n' peel tamper-proof seal and white re-sealable polypropylene flip-top closure.

Pack sizes: 30 capsules and 90 capsules.

Registration Number

This product has not yet been allocated by the regulatory authority.

Name and Address of Holder of Certificate of Registration

Amway South Africa (Pty) Ltd. Unit B1, 33 Brussels road, Spartan, Isando 1619.

Date of Publication

To be allocated by the regulatory authority.

Access to the corresponding Professional Information www.Amway.co.za

S0 Omega 3 Complex 30s
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PASIËNTINLIGTINGSTUK

SKEDULERING STATUS S0

NUTRILITE™ OMEGA-3 COMPLEX – sagte gelatien kapsules

Elke sagte gelatien kapsule bevat:

***Engraulis ringens* (Peruaanse Ansjovis), *Sardinops sagax* (Suid Afrikaanse Sardien) and *Scomba scobrus* (Makriel) oil .... 1030 mg verskaf**

Eicosapentaenoïensuur	**180 mg**
Docosahexaenoïensuur	**120 mg**
Totale Omega 3 vetsure...........	**380 mg**
Vitamiene E (d-alfa tokoferol)........	**5 mg a-TE**
Suiker vry	

Elke sagte gelatien kapsule bevat gliserol 131 mg

D34.12 Veelvuldige stof formule KOMPLEMENTÊRE MEDISYNE – GESONDHEIDSAANVULLING

Hierdie ongeregistreerde medisyne is nie geëvalueer deur SAHPRA vir die kwaliteit, veiligheid of beoogde gebruik nie. gebruik nie.

Lees alles in hierdie pamphlet versigtig want dit bevat belangrike inligting vir jou.

NUTRILITE™ OMEGA-3 COMPLEX is beskikbaar sonder 'n dokter's voorskrif vir om jou hart en brein gesondheid te ondersteun. Nietemin, moet jy NUTRILITE™ OMEGA-3 COMPLEX gebruik versigtig om die beste resultate daarvan te kry.

- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Moet nie NUTRILITE™ OMEGA-3 COMPLEX met enige person deel nie.
- Vra jou gesondheidswerker of apteker indien jy meer inligting of advies benodig sien afdeling 4.

Wat is in hierdie pamflet:

1. Wat NUTRILITE™ OMEGA-3 COMPLEX is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy NUTRILITE™ OMEGA-3 COMPLEX neem
3. Hoe om NUTRILITE™ OMEGA-3 COMPLEX te gebruik
4. Moontlike newe effekte
5. Hoe om NUTRILITE™ OMEGA-3 COMPLEX te stoor
6. Inhoud van die verpakking en ander inligting

1. Wat NUTRILITE™ OMEGA-3 COMPLEX is en waarvoor word dit gebruik

NUTRILITE™ OMEGA-3 COMPLEX bevat gekonsentreerde omega 3 polionversadigde vetsuur visolie wat eicosapentaenoïensuur en docosahexaenoïensuur tot 'n 3:2 verhouding bied. Polionversadigde vetsure word in self in die liggaam geproduseer nie en moet kom vanaf jou dieët. NUTRILITE™ OMEGA-3 COMPLEX bied 'n gerieflike manier om hierdie essensiële vetsure tot jou dieët by te voeg. Omega 3 vetsure ondersteun en handhaaf gesonde hart en breinfunksie.

Die voordelige effek vir die handhawing van normale breinfunksie word verkry met 'n daaglikse inname van 250 mg dokosaheksaensuur (DHA).

Die voordelige effek vir ondersteuning en instandhouding van hartgesondheid word verkry met 'n daaglikse inname van 250 mg van die kombinasie van Eicosapentaenoïensuur (EPA) en Docosahexaenoïensuur (DHA).

"'n Gevarieerde dieet is die doeltreffendste en veiligste manier om goeie voeding, gesondheid, liggaamsamestelling sowel as geestelike en fysieke prestasie te bereik."

2. Wat jy moet weet voordat jy NUTRILITE™ OM EGA-3 COMPLEX neem

Moenie NUTRILITE™ OMEGA-3 COMPLEX neem.

- As jy hipersensitief (allergies) vir enige van die bestanddele NUTRILITE™ OMEGA-3 COMPLEX is nie (Gelys onder afdeling 6.0)

Indien enige van die bogenoemde op jou van toepassing is, moenie hierdie medisyne neem nie, en konsultasie met jou relevante gesondheidsorgwerker.

Waarskuwings en voorsorgmaatreëls

Wees veral versigtig met NUTRILITE™ OMEGA-3 COMPLEX. Konsultasie met jou relevante gesondheidsorgwerker voor gebruik:

- Indien jy 'n operasie moet ondergaan of onlangs gehad het
- Indien jy onlangs 'n trauma gehad het
- Indien jy 'n nierprobleem het
- Indien jy onbeheerde diabetes het
- Indien jy probleme met jou lewer het. Jou dokter sal enige uitwerking wat NUTRILITE ™ OMEGA-3 COMPLEX op jou lewer kan hê met bloedtoetse monitor.
- Indien jy swanger is, beplan om swanger te word of borsvoed,
- Indien jy allergies is vir vis en soja.
- Indien jy lei aan 'n bloedversteuring
- As jy bloedverdunning medisyne
- As jy asmaties is met sensitiwiteit tot aspirien het.

Moenie die daaglikse dosering vlak sonder konsultasie met jou gesondheidsorgwerker oorskry nie. Raadpleeg jou gesondheidsorgwerker vir gebruik oor 6 maande.

Kinders en Adolessente

NUTRILITE™ OMEGA-3 COMPLEX is nie geskik vir die gebruik deur kinders onder die ouderdom van 18 jaar nie.

Ander medisyne en NUTRILITE™ OMEGA-3 COMPLEX

As jy bloedverdunner, soos warfarin, neem, sal jy dalk ekstra bloedtoetse nodig hê en jou gewone dosis van jou bloedverdunningsmedisyne moet dalk verander word.

Vertel altyd jou gesondheidverskaffer indien jy enige ander medisyne neem insluitende komplementêre en tradisionele medisyne.

Swangerskap en borsvoeding

Indien jy swanger is veral in die eerste drie maande, beplan om swanger te raak of borsvoed, raadpleeg jou dokter, apteker of ander gesondheidswerker vir advies voor jy NUTRILITE™ OMEGA-3 COMPLEX neem. Die veiligheid van NUTRILITE ™ OMEGA-3 COMPLEX tydens swangerskap en borsvoeding is nie vasgestel nie.

Bestuur en gebruik van masjinerie

NUTRILITE™ OMEGA-3 COMPLEX word nie verwag om jou bestuursvermoë te beïnvloed nie. Nietemin, moet jy nie bestuur, masjinerie gebruik of take verrig wat konsentrasie vereis totdat jy seker is dat NUTRILITE™ OMEGA-3 COMPLEX jou vermoë nadelig beïnvloed veilig nie. (Sien Moontlike Newe effekte).

Belangrike inligting oor sekere van die bestanddele in NUTRILITE™ OMEGA-3 COMPLEX:

NUTRILITE™ OMEGA-3 COMPLEX is afkomstig vanaf seekosse en bevat sojaboon olie. Indien jy allergies is vir vis of soja, moenie hierdie gesondheidsaanvulling gebruik nie. NUTRILITE™ OMEGA-3 COMPLEX Bevat gliserol en kan 'n effek hê op jou bloedsuiker vlakke indien jy diabetes mellitus het. Indien jy deur jou dokter in kennis gestel was dat jy intolerant is teenoor sekere suikers, kontak jou dokter voor jy NUTRILITE™ OMEGA-3 COMPLEX neem.

3. Hoe om NUTRILITE™ OMEGA-3 COMPLEX te neem

Neem NUTRILITE™ OMEGA-3 COMPLEX altyd presies soos aangedui op die pamphlet of soos deur jou dokter of apteker aangedui. Raadpleeg jou dokter, apteker of verpleegster indien jy nie seker is nie. Die gewone dosis vir Volwassenes is: Neem een kapsule drie keer per dag, verkieslik met maaltye of soos deur jou gesondheidswerker aanbeveel. Moenie die aanbevole daaglikse dosis oorskry nie tensy deur jou dokter aanbeveel.

Moenie die aanbevole daaglikse dosis oorskry nie tensy deur jou dokter aanbeveel.

As jy meer NUTRILITE™ OMEGA-3 COMPLEX geneem het as wat jy moet

In geval van 'n oordosis, raadpleeg jou dokter of apteker. As daar nie een beskikbaar is nie, kontak die naaste hospital of vergiftingssentrum.

As jy vergeet het om NUTRILITE™ OMEGA-3 COMPLEX te neem

Moenie 'n dubbele dosis neem om die vergete dosis in te haal nie.

4. Moontlike newe effekte

NUTRILITE™ OMEGA-3 COMPLEX kan newe effekte hê. Nie al die newe effekte is gerapporteer van NUTRILITE™ OMEGA-3 COMPLEX en ingesluit in hierdie pamflet nie. Indien jou algemene gesondheid agteruitgaan of as jy enige onnodige effekte ondervind terwyl jy NUTRILITE™ OMEGA-3 COMPLEX gebruik, kontak asseblief jou dokter, apteker of ander gesondheidswerker vir advies. Sekere minder algemene newe effekte NUTRILITE™ OMEGA-3 COMPLEX kan ernstig wees. Indien die volgende gebeur, stop gebruik van NUTRILITE™ OMEGA-3 COMPLEX en vertel jou dokter onmiddelik of gaan na die naaste ongevalle afdeling of jou naaste hospitaal toe, omdat jy onmiddelike mediese aandag of hospitalisasie benodig:

Algemene newe effekte (voorkoms in 1 tot 10 gebruikers in 100):

Maag probleme soos abdominale swelling, pyn, konstipasie, diarree, slegte spysvertering (dispepsie), winde, winde opbreek, siek voel (naarheid), siek te wees (braking).

Minder algemene newe effekte (voorkoms in 1 tot 10 gebruikers in 1000):

- hoë bloedsuiker vlakke
- jig
- duiseligheid
- probleme met smaak
- hoofpyn
- lae bloeddruk
- neusbloedings
- bloed in stoelgang
- uitslag

Rare newe effekte (voorkoms in 1 tot 10 gebruikers in 10 000):

- indien jy enige ander newe effekte kry, praat met jou dokter, apteker of verpleegster. Dit sluit in moontlike newe effekte nie allergiese reaksies nie.
- Verhoogde rooi veluitslag (korwe of urtikarie)
- Lewer afwykings, met moontlike veranderinge in sekere bloedtoetse

Rapportering van newe effekte

Praat met jou dokter, apteker of verpleegster as jy newe effekte ervaar.Jy kan ook newe effekte by SAHPRA aanmeld:

SAHPRA publikasies: SAHPRA via die "6.04 Rapporteer vorm vir ongewenste geneesmiddelreaksies", wat aanlyn gevind kan word. https://www.sahpra.org.za/Publications/Index/8.

Botswana publikasies: https://www.bomra.co.bw/index.php/services/patient-safety-monitoring.

Nambia publikasies: Rapporteer vorm vir ongewenste geneesmiddelreaksies (Veiligheidsgeel vorm) https://nmrc.gov.na/documents/81630/410067/Safety+Yellow+Form.pdf/8cbbf343-3cf8-dba3-7ec1-50b881fdab26.

Mag ook aan Amway Suid Afrika (Edms) Beperk rapporteer deur die volgende e-pos te gebruik: Regulatory_Department@Amway.com.

Deur newe effekte te rapporteer, kan jy help om meer inligting te verskaf teenoor die veiligheid van NUTRILITE™ OMEGA-3 COMPLEX.

5. Hoe om NUTRILITE™ OMEGA-3 COMPLEX te stoor

Stoor alle medisyne buite die bereik en sig van kinders. Stoor in die oorspronklike verpakking/houer. Hou die houer dig toe en beskerm teen lig en vog. Stoor teen of benede 25°C. Moenie NUTRILITE™ OMEGA-3 COMPLEX gebruik na die vervaldatum op die etiket nie. Die vervaldatum verwys na die laaste dag van daardie maand. Moenie NUTRILITE™ OMEGA-3 COMPLEX gebruik, indien die kapsules van kleur of vorm verander het nie.

Wegdoening van NUTRILITE™ OMEGA-3 COMPLEX

Neem alle ongebruikte medisyne terug na u apteker. Moenie ongebruikte medisyne in dreine of rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat NUTRILITE™ OMEGA-3 COMPLEX Bevat

Die aktiewe bestanddele is omega 3 vetsure, eicosapentaenoïensuur, docosahexaenoïensuur en vitamiene E.

Die ander bestanddele is gelatien, gliserol, sojaboon olie en water.

Hoe NUTRILITE™ OMEGA-3 COMPLEX lyk en die inhoud van die houer

Dit het 'n ongedrukte kleurlose sagte gelatien capsules wat ligte geel olie bevat.

Dit is beskikbaar in wit HD poliëtileen houer met 'n oplig peuterbestande seël en 'n wit herseelbare polipropileen oplig doppie.

Verpakkingsgrootte: 30 kapsules en 60 kapsules.

Registrasie Nommer Hierdie produk is nog nie deur plaaslike owerheid geevalueer nie.

Naam en besigheidsadres van die houer van die registrasiesertifikaat

Amway Suid Afrika (Edms) Bpk, Eenheid B1, Brussels weg 33, Spartan, Isando 1619.

Datum van Publikasie Moet toegedien word deur die plaaslike owerheid.

Toegang tot die ooreenstemmende Professionele inligting www.Amway.co.za