

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

SO

NUTRILITE™ KIDS OMEGA-3 – soft gelatin chewable capsules.
Cholecalciferol and concentrated Omega-3 triglycerides-fish oil
Contains sugar (Glycerol, Sucrose and Trehalose)

Each soft gelatin chewable capsule contains 105 mg of Glycerol, 275 mg of Sucrose and 275 mg of Trehalose.

COMPLEMENTARY MEDICINE – HEALTH SUPPLEMENT

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

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

NUTRILITE™ KIDS OMEGA-3 is available without a doctor's prescription, for you to maintain good health. Nevertheless, you still need to use NUTRILITE™ KIDS OMEGA-3 carefully to get the best results from it.

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

What is in this leaflet

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

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

NUTRILITE™ KIDS OMEGA-3 contains concentrated omega-3 polyunsaturated fatty acids from fish oil and vitamin D. Fish oil is the source of docosahexaenoic acid (DHA) and eicosapentaenoic acid (EPA). Omega-3 fatty acids support normal support development of brain, eyes and nerves. Vitamin D helps support normal growth and bone development. It also contributes to the normal functioning of their immune system.

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

Do not take NUTRILITE™ KIDS OMEGA-3

- If you are hypersensitive (allergic) to any of the ingredients (See list in section 6.0)
- If you are allergic to fish, shellfish and seafood

Warnings and precautions

NUTRILITE™ KIDS OMEGA-3 is derived from fish which may cause allergic reactions. If you are allergic to fish, shellfish and seafood do not take this complementary medicine. Do not exceed daily dosage level without consulting a relevant health care provider.

Consult a relevant health care provider for use beyond 6 months.

Other medicines and NUTRILITE™ KIDS OMEGA-3

Consult a relevant health care provider before use if you suffer from a bleeding disorder, take blood thinning medicines or are asthmatic with sensitivity to aspirin. Always tell your health care provider if you are taking any other medicine including all complementary or traditional medicines.

NUTRILITE™ KIDS OMEGA-3 with food, drink and alcohol

NUTRILITE™ KIDS OMEGA-3 should be given with food. This is to help lower the chances of side effects that affect the stomach.

Pregnancy, breastfeeding and fertility

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 health care provider for advice before taking this complementary medicine. Safety of NUTRILITE™ KIDS OMEGA-3 in pregnancy and breastfeeding has not been established.

Driving and using machines

NUTRILITE™ KIDS OMEGA-3 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™ KIDS OMEGA-3 does not adversely affect your ability to do so safely (See Possible Side-effects).

Important information about some of the ingredients of NUTRILITE™ KIDS OMEGA-3:

NUTRILITE™ KIDS OMEGA-3 Contains glycerol, sucrose and trehalose (source of glucose), which are sugars and may have an effect on the control of your blood sugar if you have diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking NUTRILITE™ KIDS OMEGA-3.

3. How to take NUTRILITE™ KIDS OMEGA-3

Always take NUTRILITE™ KIDS OMEGA-3 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. Children 4 years and older: Take one soft gelatin chewable capsule per day preferably with a liquid or as directed by your healthcare provider. Do not exceed the recommended daily dose unless directed by your doctor.

If you take more NUTRILITE™ KIDS OMEGA-3 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™ KIDS OMEGA-3

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

4. Possible side-effects

NUTRILITE™ KIDS OMEGA-3 can have side effects. Not all side effects reported for NUTRILITE™ KIDS OMEGA-3 is included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NUTRILITE™ KIDS OMEGA-3, please consult your health care provider for advice.

Some less frequent side effects of OMEGA-3 fatty acids supplementation can be serious. If any of the following happen to you, stop taking NUTRILITE™ KIDS OMEGA-3 and tell your doctor immediately or go to the casualty department at your nearest hospital as you will need immediate medical attention or hospitalisation:

Common side effects (occur in 1 to 10 users in 100):

- Stomach problems like abdominal distension
- constipation
- diarrhoea
- 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):

- allergic reactions
- itchy rash (hives or urticaria)
- liver disorders, with possible changes in the results of certain blood tests

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 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/8ccbf343-3cf8-dba3-7ec1-50b881fdab26> By reporting side effects, you can help provide more information on the safety of NUTRILITE™ KIDS OMEGA-3.

5. How to store NUTRILITE™ KIDS OMEGA-3

Store all medicines out of the sight and reach of children. Store in the original package/ container. Store at or below 25 °C. Keep the container tightly closed to protect from light and moisture. Do not use NUTRILITE™ KIDS OMEGA-3 after the expiry date stated on the label. The expiry date refers to the last day of that month. Do not use NUTRILITE™ KIDS OMEGA-3, if you notice the capsules have changed shape or colour.

Disposal of NUTRILITE™ KIDS OMEGA-3

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™ KIDS OMEGA-3 contains

Each Soft Gelatin Capsule Contains:

Active Substances	Quantity
Cholecalciferol (Vitamin D3)	4 µg
Concentrated Omega-3 triglycerides-Fish oil mix of:	403 mg
Engraulis ringens (Peruvian Anchovy), Engraulis encrasiculus (European Anchovy), Sardina pilchardus (European Pilchard), Scomber colias (Atlantic chub mackerel) and Scomber japonicus (Pacific chub mackerel).	
providing:	
Eicosapentaenoic acid	45 mg
Docosahexaenoic acid	215 mg
Total Omega 3 fatty acids	288 mg

The other ingredients are purified water, sucrose, trehalose, alpha-tocopherol, ascorbyl palmitate, bovine gelatin, citric acid, glycerol, medium triglycerides, tutti frutti flavour, paprika extract colour, canola oil, sunflower oil, trisodium citrate, medium chain triglycerides, mono- and diglycerides of fatty acids.

The capsule shell is made up of bovine gelatin, glycerol, medium-chain triglycerides, mono- and diglycerides of fatty acids and purified water.

What NUTRILITE™ KIDS OMEGA-3 looks like and contents of the pack

Orange, round shaped, fruity flavour.

They are available in blister pack of 30 soft gelatin chewable capsules.

Each blister strip contains 15 soft gelatin chewable capsules packed in white carton box with two tamper-evident seals.

Registration Number

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

Name and Address of Applicant/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

PASIËNTINLITINGSTUK

SKEDULERINGSTATUS

SO

NUTRILITE™ KIDS OMEGA-3 – sagte gelatien koubare kapsules.
Cholekalciferol en gekonsentreerde Omega-3 trigliseriede-vis olie.
Bevat suiker (Gliserol, Sukrose en Trehalose)

Elke sagte gelatien koubare kapsule bevat 105 mg gliserol, 275 mg sukrose en 275 mg trehalose.

KOMPLEMENTÈRE MEDISYNE – GESONDHEIDSAANVULLING
Lees hierdie hele inligtingstuk sorgvuldig aangesien dit belangrike inligting vir jou bevat.

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

NUTRILITE™ KIDS OMEGA-3 is beskikbaar vir jou sonder 'n dokters voorskrif vir die instandhouding van goeie gesondheid. Nietemin, moet jy egter steeds NUTRILITE™ KIDS OMEGA-3 versigtig gebruik om die beste resultate daarvan te kry.

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

Wat is in hierdie pamphlet:

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

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

NUTRILITE™ KIDS OMEGA-3 bevat gekonsentreerde omega-3 poli-onversadigde vetsure vanaf visolie en Vitamiene D. Visolie is 'n bron van docosahexaenoënsuur (DHA) en eicosapentaenoënsuur (EHA). Omega-3 vetsure ondersteun die ontwikkeling van die brein, oë en senuwees. Vitamiene D help om ondersteuning te bied vir normale groei en been ontwikkeling. Dit dra ook by tot die normale funksionering van hulle immuunstelsel.

2. Wat jy moet weet voordat jy NUTRILITE™ KIDS OMEGA-3 neem

Moenie NUTRILITE™ KIDS OMEGA-3 gebruik

- As jy hipersensitief (allergies) vir enige van die bestanddele is nie (Gelys onder afdeling 6.0)
- Indien jy allergies is vir vis, skulpvis en seekosse

Waarskuwings en voorsorgmaatreëls

NUTRILITE™ KIDS OMEGA-3 is afkomstig van vis wat allergiese reaksies kan veroorsaak. Indien jy allergies is vir vis, skulpvis en seekosse moenie hierdie komplementêre medisyne gebruik nie.

Moet nie die aangeduide dosis oorskry nie, sonder bevestiging van jou gesondheidswerker.

Raadpleeg jou gesondheidswerker indien gebruik 6 maande oorskry.

Ander medisyne en NUTRILITE™ KIDS OMEGA-3

Raadpleeg jou gesondheidswerker voor gebruik indien jy lei aan bloed awfykings, die neem van bloedverdunners of as jy asmaties met sensitiwiteit tot aspirien.

Vertel altyd jou gesondheidverskaffer as jy enige ander medisyne neem insluitende alle komplementêre of traditionele medisyne.

NUTRILITE™ KIDS OMEGA-3 saam met voedsel, drank en alkohol

NUTRILITE™ KIDS OMEGA-3 moet gegee word saam met kos. Dit is om die kans tot newe effekte wat die maag affekteer te verminder.

Swangerskap en borsvoeding

Indien jy swanger is of borsvoed, of indien jy dink jy kan swanger wees of beplan om swanger te raak, raadpleeg jou dokter, apteker of ander gesondheidswerker vir advies voor jy hierdie komplementêre medisyne neem. Veiligheid tydens swangerskap of borsvoeding is nie vasgestel nie.

Bestuur en gebruik van masjinerie

Dit waarskynlik dat dit nie die bestursvermoë of die vermoë om masjinerie te gebruik of om daarmee te werk beïnvloed nie. Nietemin, moet jy nie bestuur, masjinerie gebruik of take verrig wat konsentrasie vereis totdat jy seker is dat NUTRILITE™ KIDS OMEGA-3 jou vermoë daarvan kan negatief beïnvloed nie. (Sien Moontlike Newe effekte).

Belangrike inligting oor sommige van die bestanddele in NUTRILITE™ KIDS OMEGA-3:

NUTRILITE™ KIDS OMEGA-3 bevat **Gliserol, Sukrose en Trehalose** wat suikers is en kan 'n effek hê op jou bloedsuikervlakte 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™ KIDS OMEGA-3 neem.

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

Neem NUTRILITE™ KIDS OMEGA-3 altyd presies soos aangedui op die etiket of soos deur jou dokter of apteker aangedui. Raadpleeg jou dokter, apteker of verpleegster indien jy nie seker is nie.

Kinders 4 jaar en ouer: Neem een sagte gelatien koubare kapsule per dag, verkiesslik met 'n vloeistof of soos aangedui deur u gesondheidswerker. Moenie die daagliks dosering oorskry indien nie aanbeveel was deur jou dokter nie.

As jy meer NUTRILITE™ KIDS OMEGA-3 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 vergiftigingscentrum.

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

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

4. Moontlike newe effekte

NUTRILITE™ KIDS OMEGA-3 kan newe effekte hê. Nie al die newe effekte is gerapporteer van NUTRILITE™ KIDS OMEGA-3 en ingesluit in hierdie pamphlet nie. Indien jou algemene gesondheid agteruitgaan of as jy enige onnodige effekte ondervind terwyl jy NUTRILITE™ KIDS OMEGA-3 gebruik, kontak asseblief jou dokter, apteker of ander gesondheidswerker vir advies.

Sommige minder algemene newe effekte met die neem van omega-3-vetsure aanvullings. Indien enige van die volgende met jou gebeur, stop om NUTRILITE™ KIDS OMEGA-3 te gebruik en vertel jou dokter onmiddellik of gaan na die naaste ongevalle afdeling of jou naaste hospitaal toe:

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

- Maag probleme soos abdominale swelling
- pyn,
- konstipasie
- diarree,
- slechte spysvertering (dispepsie)
- wind
- wind opbrek
- siek voel (naarheid)
- siek te wees (braking).

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

- hoë bloedsuikervlakte
- jig
- duiselheid
- probleme met smaak
- hoofpyn
- lae bloeddruk
- neusbloedings
- bloed in stoelgang
- uitslag

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

- allergiese reaksies
- Verhoogde rooi veluitslag (korwe of urtikarie)
- Lewer awfykings, met moontlike veranderinge in sekere bloedtoetse

Rapportering van newe effekte

Praat met jou dokter, apteker of verpleegster as jy newe effekteervaar.

Jy kan ook newe effekte by SAHPRA aannemel:

SAHPRA publikasies: SAHPRA via die "6.04 Adverse Drug Reaction Reporting Form", 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: Adverse Medicine Reaction Reporting Form <http://www.nmrc.com.na/downtipc>

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

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

Stoor alle medisyne buite sig en bereik van kinders.

Stoor in die oorspronklike verpakking/houer.

Stoor teen of benede 25°C. Hou die houer dig toe en beskerm teen lig en vog.

Moenie NUTRILITE™ KIDS OMEGA-3 gebruik na die verval datum op die etiket nie. Die verval datum verwys na die laaste dag van daardie maand.

Moenie NUTRILITE™ KIDS OMEGA-3 gebruik, indien die kapsules van kleur of vorm verander het nie.

Wegdoening van NUTRILITE™ KIDS OMEGA-3

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

6. Inhoud van die verpakking en ander inligting

Wat NUTRILITE™ KIDS OMEGA-3 bevat

Aktiewe bestanddele	Hoeveelheid
Cholekalciferol (Vitamiene D3)	4 µg
Gekonsentreerde Omega-3 trigliseriede-vis olie mengsel van:	403 mg
Engraulis ringens (Peruaanse Ansjovis), Engraulis encrasiculus (Europese Ansjovis), Sardina pilchardus (Europese Sardien), Scomber colias (Atlantiese vet makrel) and Scomber japonicus (Stille oseaan vet makrel).	
wat verskaf:	
Eicosapentaenoënsuur	45 mg
Docosahexaenoënsuur	215 mg
Totale Omega 3 vetsure	288 mg

Die ander bestanddele is gesuiwerde water, sukrose, trehalose, alpha-tokoferol, askorbielpalmitaat, varkgelatien, sitroensuur, gliserol, medium trigliseriede, tutti frutti geursel, paprika ekstrak kleurstof, kanola olie, sonneblom olie, natrium trisitraat, medium ketting trigliseriede, mono en digliseriede van vetsure.

Die kapsuledop bestaan uit varkgelatien, gliserol, medium ketting trigliseriede, mono en digliseriede van vetsure en gesuiwerde wate

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

Oranje, rond vormige, vrugte geur.

Dit is beskikbaar in stulpverpakking van 30 sagte gelatien koubare kapsules.

Elke stulpverpakking bevat 15 sagte gelatien koubare capsules gepak in 'n wit karton boks met twee peuterbestande seëls.

Registrasie Nommer

Hierdie produk is nog nie deur die plaaslike owerheid geëvalueer nie.

Naam en besigheidsadres van die houer van die registrasiesertifikaat

Amway Suid Afrika (Edms) Bpk
Beperk, 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