

SOLAL® OMEGA-ALL

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Unscheduled

PROPRIETARY NAME AND DOSAGE FORM

SOLAL® OMEGA-ALL, softgel capsules

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

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

SOLAL® OMEGA-ALL is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use SOLAL® OMEGA-ALL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SOLAL® OMEGA-ALL with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

WHAT SOLAL® OMEGA-ALL CONTAINS

The active substances are:

Fish oil	500,4 mg
providing:	
Eicosapentaenoic acid (EPA)	75,0 mg
Docosahexaenoic acid (DHA)	50,0 mg
<i>Linum usitatissimum</i> L. (Flaxseed) oil	400,0 mg
providing:	
Alpha-linolenic acid (ALA)	153,0 mg
Krill oil (<i>Euphausia superba</i>)	100,0 mg
providing:	
Eicosapentaenoic acid (EPA)	12,0 mg
Docosahexaenoic acid (DHA)	5,5 mg

The other ingredients are:

Bovine gelatine, dl-alpha-tocopherol acetate, glycerine, silicon dioxide and water.

WHAT SOLAL® OMEGA-ALL IS USED FOR

Category D Complementary Medicine
Discipline 34.12 Health Supplements. Multiple substance formulation

SOLAL® OMEGA-ALL provides essential omega-3 fatty acids for the maintenance of good health.

It helps support cardiovascular health and aids in supporting cognitive health and brain function.

BEFORE YOU TAKE SOLAL® OMEGA-ALL

Do not take SOLAL® OMEGA-ALL if you are hypersensitive (allergic) to any of the ingredients.

Do not take SOLAL® OMEGA-ALL if you are hypersensitive (allergic) to fish and/or crustacean shellfish.

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

Take special care with SOLAL® OMEGA-ALL

SOLAL® OMEGA-ALL contains crustacean shellfish. Hypersensitivity/allergy has been known to occur with shellfish, if this occurs, discontinue use.

Consult a relevant healthcare provider before use:

- If you are asthmatic with sensitivity to aspirin
- If you take blood thinning medicines or suffer from a bleeding disorder
- If you are pregnant or breastfeeding. You should consult a relevant healthcare provider for use beyond 6 months.

Taking SOLAL® OMEGA-ALL with food and drink

Take SOLAL® OMEGA-ALL after food.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking SOLAL® OMEGA-ALL. Safety during pregnancy and breastfeeding has not been established.

Important information about some of the ingredients of SOLAL® OMEGA-ALL

Sugar free

Taking other medicines with SOLAL® OMEGA-ALL

Always tell your healthcare provider if you are taking any other medicine.

Fish oil (as in SOLAL® OMEGA-ALL) may have antiplatelet effects and may increase the risk of bleeding if used with anticoagulant/ blood thinners (e.g. warfarin) or antiplatelet medicines (e.g. aspirin). Concomitant use of Krill oil (as in SOLAL® OMEGA-ALL) and anti-diabetes medicines such as metformin might have additive effects in lowering blood glucose levels and increase the risk of hypoglycaemia (low blood sugar).

HOW TO TAKE SOLAL® OMEGA-ALL

Do not share medicines prescribed for you with any other person. Always take SOLAL® OMEGA-ALL exactly as instructed. You should check with your doctor or pharmacist if you are unsure.

The usual dosage is:

Adults: Take 2 capsules daily after food.
Children 4-12 years of age: Give 1 capsule once daily (capsule can be opened and mixed into food).

If you take more SOLAL® OMEGA-ALL than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of SOLAL® OMEGA-ALL
Do not take a double dose to make up for forgotten individual doses.

POSSIBLE SIDE EFFECTS

SOLAL® OMEGA-ALL can have side effects. Side effects may include abdominal pain, bad breath, fishy aftertaste, heartburn, increased low-density lipoprotein (LDL) cholesterol levels, loose stools, nausea, and rash.

Not all side effects reported for SOLAL® OMEGA-ALL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking SOLAL® OMEGA-ALL, please consult your healthcare provider for advice.

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

STORING AND DISPOSING OF SOLAL® OMEGA-ALL

Store all medicines out of reach of children.
Store at or below 25 °C.
Store in the original package / container.
Keep the container tightly closed.
Protect from light.
Protect from moisture.
Do not store in a bathroom.
Do not use after the expiry date stated on the label / bottle.
Do not use SOLAL® OMEGA-ALL if you notice visible signs of deterioration.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF SOLAL® OMEGA-ALL

A white plastic container with a white plastic screw cap and a seal for protection, containing 60 softgel capsules.

IDENTIFICATION OF SOLAL® OMEGA-ALL

A clear, oblong, softgel capsule containing a light orange transparent oil.

REGISTRATION NUMBER

TBA

DATE OF REGISTRATION

TBA

PROFESSIONAL INFORMATION

For further information refer to the Professional Information of the product.

NAME AND ADDRESS OF REGISTRATION HOLDER

Ascendis Consumer Brands (Pty) Ltd
1 Carey Street
Wynberg, Gauteng 2090
South Africa
+27 11 036 9420

DATE OF PUBLICATION OF THE PROFESSIONAL INFORMATION

TBA

SOLAL® OMEGA-ALL

PASIËNTINLIGTINGSBLAADJIE

SKEDULERINGSSTATUS

Ongeskeduleer

HANDELSNAAM EN DOSEERVORM

SOLAL® OMEGA-ALL, sagtegel kapsules

Lees die hele inligtingsblaadjie noukeurig deur, dit bevat belangrike inligting vir jou

'n Dieët met verskeidenheid is die doeltreffendste en veiligste manier om goeie voeding, gesondheid, liggaamsamestelling sowel as geestelike en fisiese prestasies te bewerkstellig.

SOLAL® OMEGA-ALL is beskikbaar sonder 'n doktersvoorskrif om minder ernstige siektes te behandel. Jy moet egter nogsteeds SOLAL® OMEGA-ALL versigtig gebruik om die beste resultate te verkry.

- Hou hierdie voubljiet, dit mag dalk nodig wees om dit weer te lees.
- Moenie SOLAL® OMEGA-ALL met enige ander persoon deel nie.
- Raadpleeg jou gesondheidsorgverskaffer of apteker indien jy meer inligting of advies benodig.

WAT SOLAL® OMEGA-ALL BEVAT

Die aktiewe bestanddele is:

Visolie	500,4 mg
verskat:	
Eikosapentanoësuur (EPS)	75,0 mg
Dokosaheksanoësuur (DHS)	50,0 mg
<i>Linum usitatissimum</i> L. (Vlassaad) olie	400,0 mg
verskat:	
Alfa-linoleensuur (ALA)	153,0 mg
Krillolie (<i>Euphausia superba</i>)	100,0 mg
verskat:	
Eikosapentanoësuur (EPS)	12,0 mg
Dokosaheksanoësuur (DHS)	5,5 mg

Die ander bestanddele is:

Beesgelatien, dl-alfa-tokolerolasetaat, gliserien, silikondioksied en water.

WAARVOOR SOLAL® OMEGA-ALL GEBRUIK WORD

Kategorie D Komplementêre Medisyne
Discipline 34.12 Gesondheidsaanvulling. Veelvuldige middel formule.

SOLAL® OMEGA-ALL verskat essensiële omega-3 vetsure vir die handhawing van goeie gesondheid.

Dit help om kardiovaskulêre gesondheid, kognitiewe gesondheid en breinfunksie te ondersteun.

VOORDAT SOLAL® OMEGA-ALL GEBRUIK WORD

Moenie SOLAL® OMEGA-ALL gebruik indien jy hipersensitief (allergies) is vir enige van die bestanddele nie.

Moenie SOLAL® OMEGA-ALL neem as jy hipersensitief (allergies) is vir vis en/of skaaldier skulpvvis nie.

Hierdie ongeregistreerde medisyne is nie deur SAHPRA geëvalueer vir sy gehalte, veiligheid of beoogde gebruik nie.

Neem spesiale sorg met SOLAL® OMEGA-ALL

SOLAL® OMEGA-ALL bevat skaaldier skulpvvis. Hipersensitiwiteit/ allergie is bekend om voor te kom met skulpvvis; as dit voorkom, staak gebruik.

Raadpleeg 'n relevante gesondheidsorgverskaffer voor gebruik:

- As jy asmaties is met 'n hipersensitiwiteit vir aspirien
- As jy bloedverdunningsmedikasie neem of ly aan 'n bloedahtwyking
- As jy swanger is of borsvoed.

Jy moet 'n relevante gesondheidsorgverskaffer raadpleeg vir gebruik langer as 6 maande.

Neem van SOLAL® OMEGA-ALL met voedsel en vloeistof

Neem SOLAL® OMEGA-ALL na voedsel.

Swangerskap en Borsvoeding

As jy swanger is of jou baba borsvoed, raadpleeg jou gesondheidsorgverskaffer voordat jy SOLAL® OMEGA-ALL gebruik. Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie.

Belangrike inligting in verband met sommige van die bestanddele in SOLAL® OMEGA-ALL

Suikervry

As jy ander medisyne saam met SOLAL® OMEGA-ALLneem

Stel altyd jou gesondheidsorgverskaffer in kennis indien jy enige ander medisyne gebruik.

Visolie (soos in SOLAL® OMEGA-ALL) mag antiplaattjie effekte hê en mag die risiko vir bloeding verhoog as dit saam met antikoagulerante/ bloedverdunners (bv. warfarin) of antiplaattjie medisyne (bv. aspirien) geneem word.

Gelyktydige gebruik van Krillolie (soos in SOLAL® OMEGA-ALL) en antidiabetiese medisyne soos metformien, kan bykomende effekte het in die verlagng van bloedglukose vlakke en verhoog die risiko van hipoglisemie (lae bloedsuiker).

HOE OM SOLAL® OMEGA-ALL TE GEBRUIK

Moenie jou medisyne met enige iemand anders deel nie.
Neem SOLAL® OMEGA-ALL altyd presies soos aanbeveel. Bevestig met jou dokter of apteker indien jy onseker is.

Die normale dosering is:

Volwassenes: Neem 2 kapsule daagliks na voedsel.
Kinders tussen 4 - 12 jaar oud: Gee 1 kapsule een keer daagliks (die kapsule kan oopgemaak word en die inhoud met kos gemeng word).

Indien jy meer SOLAL® OMEGA-ALL gebruik as wat jy behoort

Indien oordosering vermoed word, raadpleeg onmiddellik jou dokter of apteker. Indien geneen beskikbaar is nie, kontak die naaste hospitaal of gifteheersentrum.

Indien jy vergeet het om SOLAL® OMEGA-ALL te neem

Moenie 'n dubbele dosis neem om vir oorgeslane dosisse te vergoed nie.

MOONTLIKE NEWE-EFFEKTE

SOLAL® OMEGA-ALL kan moontlik newe-effekte veroorsaak. Newe-effekte mag insluit abdominale pyn, slegte asem, visagtige nasmaak, sootbrand, verhoogde lae-digtheid lipoproteïene (LDL) cholesterol vlakke, los stoelgang, naarheid, en uitslag.

Nie alle newe-effekte wat vir SOLAL® OMEGA-ALL aangemeld is word in hierdie voubljiet genoem nie.

Indien jou algemene gesondheid verswak of indien jy enige nadelige effekte ondervind terwyl jy SOLAL® OMEGA-ALL gebruik, moet jy asseblief jou dokter, apteker of ander gesondheidsorgverskaffer raadpleeg.

Indien jy enige newe-effekte waarneem wat nie in hierdie voubljiet genoem word nie, moet jy jou dokter of apteker daarvan vertel.

BERGING EN WEGDOEN VAN SOLAL® OMEGA-ALL

Bewaar alle medikasie buite bereik van kinders.
Bewaar teen of benede 25 °C.

Bewaar in die oorspronklike houer.

Maak die houer dig toe.

Beskermt teen vog.

Beskermt teen vog.

Moenie die produk in die badkamer bewaar nie.

Moenie na die vervaldatum wat op die etiket / bottel aangedui is, gebruik nie.

Moenie SOLAL® OMEGA-ALL gebruik indien jy enige sigbare tekens van produkafbraak opmerk nie.

Besorg enige ongebruikte medisyne terug aan jou apteker.

Moenie van ongebruikte medisyne ontstae raak in dreine of rioolstelsels nie (bv. toilette).

AANBIEDING VAN SOLAL® OMEGA-ALL

'n Wit plastiekhouer met 'n wit plastiek skroefprop en 'n seël vir beskerming, gevul met 60 sagtegel kapsules.

IDENTIFIKASIE VAN SOLAL® OMEGA-ALL

'n Deurskynende, langwerpige, sagtegel kapsule gevul met 'n deurskynende lig-oranje olie

REGISTRASIEONMMER

TBA

DATUM VAN REGISTRASIE

TBA

PROFESIONELE INLIGTING

Vervys na die voubljiet met Professionele Inligting vir meer inligting.

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT

Ascendis Consumer Brands (Pty) Ltd
1 Carey Street
Wynberg, Gauteng 2090
South Africa
+27 11 036 9420

DATUM VAN PUBLIKASIE VAN DIE PROFESIONELE INLIGTING

TBA

905M359/00

SOLAL® OMEGA-ALL

PROFESSIONAL INFORMATION

SCHEDULING STATUS

Unscheduled

PROPRIETARY NAME AND DOSAGE FORM

SOLAL® OMEGA-ALL, softgel capsules

COMPOSITION

Each capsule contains:

Fish oil	500,4 mg
providing:	
Eicosapentaenoic acid (EPA)	75,0 mg
Docosahexaenoic acid (DHA)	50,0 mg
<i>Linum usitatissimum</i> L. (Flaxseed) oil	400,0 mg
providing:	
Alpha-linolenic acid (ALA)	153,0 mg
Krill oil (<i>Euphausia superba</i>)	100,0 mg
providing:	
Eicosapentaenoic acid (EPA)	12,0 mg
Docosahexaenoic acid (DHA)	5,5 mg

Inactive ingredients:

Bovine gelatine, dl-alpha-tocopherol acetate, glycerine, silicon dioxide and water.

PHARMACOLOGICAL CLASSIFICATION

Category D Complementary Medicine
Discipline 34.12 Health Supplements. Multiple substance formulation

PHARMACOLOGICAL ACTION

Fish oil and Krill oil are sources of omega-3 fatty acids as well as eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) for the maintenance of good health.

Fish oil helps support cardiovascular health and helps support cognitive health and brain function.

Flaxseed oil is one of the richest sources of alpha-linolenic acid (ALA) a precursor of EPA and DHA in the body. Flaxseed oil might have beneficial cardiovascular effects. There is preliminary evidence that a low-fat diet plus flaxseed oil can increase systemic arterial elasticity, which might improve circulatory function.

INDICATIONS

SOLAL® OMEGA-ALL provides essential omega-3 fatty acids for the maintenance of good health.

It helps support cardiovascular health and aids in supporting cognitive health and brain function.

CONTRAINDICATIONS

Hypersensitivity (allergy) to any of the ingredients of SOLAL® OMEGA-ALL and/or fish or crustacean shellfish.

WARNINGS and SPECIAL PRECAUTIONS

SOLAL® OMEGA-ALL contains crustacean shellfish. Hypersensitivity/allergy has been known to occur with shellfish, if this occurs, discontinue use.

Exercise caution in patients who suffer from a bleeding disorder, take blood-thinning medicines or are asthmatic with sensitivity to aspirin (see **INTERACTIONS**).

Patients who are pregnant or breastfeeding should consult a relevant healthcare provider prior to use.

A relevant healthcare provider should be consulted for use beyond 6 months.

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

INTERACTIONS

Fish oil (as in SOLAL® OMEGA-ALL) may have antiplatelet effects and may increase the risk of bleeding if used with anticoagulant (e.g. warfarin) or antiplatelet medicines (e.g. aspirin).

Concomitant use of Krill oil (as in SOLAL® OMEGA-ALL) and anti-diabetes medicines such as metformin might have additive effects in lowering blood glucose levels and increase the risk of hypoglycaemia.

HUMAN REPRODUCTION

Safety during pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE

Adults: Take 2 capsules daily after food.
Children 4-12 years of age: Give 1 capsule once daily (capsule can be opened and mixed into food).

SIDE EFFECTS

Side effects may include abdominal pain, bad breath, fishy aftertaste, heartburn, increased low-density lipoprotein (LDL) cholesterol levels, loose stools, nausea, and rash.

Hypersensitivity/allergy has been known to occur with shellfish; if this occurs, discontinue use.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Treatment should be symptomatic and supportive. In the case of accidental overdose of the product, contact the nearest hospital or poison control centre.

IDENTIFICATION

A clear, oblong, softgel capsule containing a light orange transparent oil.

PRESENTATION

A white plastic container with a white plastic screw cap and a seal for protection, containing 60 softgel capsules.

STORAGE INSTRUCTIONS

Store at or below 25 °C. Keep the container tightly closed. Protect from light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

TBA

DATE OF REGISTRATION

TBA

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

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