

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

34.6 Fats, Oils and Fatty Acids

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

SPM ACTIVE®, 60 Capsules

COMPOSITION

Each one (1) capsule of SPM ACTIVE® contains the following actives:

Fish oil (Lipinova®) standardised to 17-HDHA, 18-HEPE + 14-HDHA	500 mg
Omega-3 fatty acids	337,5 mg
DHA (Docosahexaenoic acid)	162,5 mg
EPA (Eicosapentaenoic acid)	100 mg
17-HDHA (17-hydroxy-docosahexaenoic acid)	120 µg
18-HEPE (18-hydroxy-eicosapentaenoic acid)	112,5 µg
14-HDHA (14-hydroxy-docosahexaenoic acid)	55 µg

Inactive Ingredients: Gelatin, glycerol, silica, tocopherol-rich extracts.

Contains: Fish (anchovy, sardine, and mackerel).

This product is suitable for non-GMO, gluten & dairy free (Sugar Free)

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

SPM ACTIVE® provides support for the body's natural processes associated with maintaining comfort. Formulated with omega-3 fish oil, it is designed to help sustain physiological responses involved in promoting balance and overall wellbeing.

Ingredient	Use for Ingredient
Fish oil (Lipinova®) standardised to 17-HDHA, 18-HEPE + 14-HDHA	Supports cardiovascular health, inflammation modulation, and cognitive function.
Omega-3 fatty acids	Promotes heart, brain, and joint health while reducing inflammation.
DHA (Docosahexaenoic acid)	Supports brain development, cognitive function, and eye health.
EPA (Eicosapentaenoic acid)	Reduces inflammation and supports heart and joint health.
17-HDHA (17-hydroxy-docosahexaenoic acid)	Acts as a pro-resolving mediator to modulate inflammation and enhance tissue repair.
18-HEPE (18-hydroxy-eicosapentaenoic acid)	Supports the resolution of inflammation and immune system balance.
14-HDHA (14-hydroxy-docosahexaenoic acid)	Contributes to inflammation resolution and promotes cellular health.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take SPM ACTIVE® if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare professional before taking this supplement. Surgery: SPM ACTIVE® might increase the risk of bleeding during and after surgery. Stop using SPM ACTIVE® at least 2 weeks before a scheduled surgery.

INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine. It is possible that exposure of certain supplement ingredients may interfere with certain medications. (See Warnings & Special precautions)

DOSAGE AND DIRECTIONS FOR USE

Adults: Take one (1) capsule daily, or up to three (3) per day or as directed by your healthcare practitioner. Do not take more than the recommended dose.



KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

See side-effects. Treatment: Discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.

WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: bleeding disorders, liver disease, uncontrolled diabetes, haemorrhagic stroke. If you are taking the following medication, please consult with your healthcare professional before taking: Anticoagulants (e.g., warfarin, aspirin), antiplatelet drugs, and NSAIDs (increased risk of bleeding), Antihypertensives (may enhance blood pressure-lowering effects), anticoagulants, immunosuppressants (may alter immune response), statins (potential additive lipid-lowering effect). If any of the following happens, stop using SPM ACTIVE® and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions— rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing;
- These are all very serious effects. If you have them, you may have had a serious reaction to SPM ACTIVE®. You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare professional if they continue):

- nausea/vomiting, Mild gastrointestinal symptoms (e.g., indigestion, flatulence).

These are all very serious effects. If you have them, you may have had a serious reaction to SPM ACTIVE®. You may need urgent medical attention or hospitalisation. Seek advice from a healthcare professional if you have any medical condition. Discontinue use immediately should any adverse reaction occur. Read this leaflet carefully because it contains important information for you. This product is available without a doctor's prescription.

- Keep this leaflet. You may need to read it again.
- Do not share medication with any other person.
- Ask your pharmacist if you need more information or advice.
- You must consult a doctor should your condition worsen or does not improve.

DO NOT USE THIS PRODUCT:

- If you are hypersensitive (allergic) to any of the ingredients listed.
- Do not accept this package if seals are broken.

STORAGE INSTRUCTION

Store in a cool, dark place, below 25 °C.

Protect from direct sunlight and heat.

Store in the original bottle.

Keep the bottle tightly closed.

Replace the protective cap after each use.

Do not use after the expiry date stated on the bottle.

Do not use SPM ACTIVE® if you notice visible signs of deterioration.

IDENTIFICATION

Clear, oval, softgel capsule with yellow fill.

PRESENTATION

A white 175 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

SIDE EFFECTS

Should your general health worsen, or if you experience any untoward effects while being exposed to this product, please consult your doctor, pharmacist or other healthcare professional for advice.

REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

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

NAME AND BUSINESS ADDRESS OF APPLICANT

Distributed by:

Amipro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension,
Sandton, 2146, Tel: 011-802-8101

DATE OF PUBLICATION

To be allocated by the regulatory authority.

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PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: **50**

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.6 Vette, olies en vetsure

HANDELSNAAM EN DOSEERVORM,

SPM ACTIVE®, 60 Kapsules

SAMESTELING

Elke een (1) kapsule SPM ACTIVE® bevat die volgende aktiewe stowwe:

Visolie (Lipinova®) gestandaardiseer tot 17-HDHA,	500 mg
18-HEPE + 14-HDHA	
Omega-3-vetsure	337,5 mg
DHA (Dokosaheksaensuur)	162,5 mg
EPA (Eicosapentaensuur)	100 mg
17-HDHA (17-hidroksi-dokosaheksaensuur)	120 µg
18-HEPE (18-hidroksi-eikosapentaensuur)	112,5 µg
14-HDHA (14-hidroksi-dokosaheksaensuur)	55 µg

Onaktiewe bestanddele: Gelatien, gliserol, silika, tokoferoliese ekstrakte.

Bevat: Vis (ansjovis, sardien en makriel).

Hierdie produk is geskik vir nie-GGO, gluten en suiwelvry (suikervry)

FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

AANDUING EN FARMAKOLOGIESE WERKING

SPM ACTIVE® bied ondersteuning vir die liggaam se natuurlike prosesse wat verband hou met die handhawing van gemak. Geformuleer met omega-3 visolie, is dit ontwerp om fisiologiese reaksies te help onderhou wat betrokke is by die bevordering van balans en algehele welstand.

INTERAKSIES

Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne gebruik. Dit is moontlik dat blootstelling van sekere aanvullingsbestanddele met sekere medisyne 'n interaksie mag hê. (Sien **Waarskuwings** en **Spesiale voorsorgmaatreëls**)

DOSES EN AANWYSINGS VIR GEBRUIK

Volwasse: Neem daaglik twee (2) kapsules of soos voorgeskryf deur jou gesondheidspraktisyn.

Moenie meer as die aanbevole dosis neem nie.

Bestanddeel	Gebruik vir bestanddeel
Visolie (Lipinova®) gestandaardiseer tot 17-HDHA, 18-HEPE + 14-HDHA	Ondersteun kardiovaskulêre gesondheid, inflammasiemodulasie en kognitiewe funksie.
Omega-3-vetsure	Bevorder hart-, brein- en gewrigsgesondheid terwyl inflammasie verminder word.
DHA (Dokosaheksaensuur)	Ondersteun breinontwikkeling, kognitiewe funksie en ooggesondheid.
EPA (Eicosapentaensuur)	Verminder inflammasie en ondersteun hart- en gewrigsgesondheid.
17-HDHA (17-hidroksi-dokosaheksaensuur)	Tree op as 'n pro-oplossende bemiddelataar om inflammasie te moduleer en weefselherstel te verbeter.
18-HEPE (18-hidroksi-eikosapentaensuur)	Ondersteun die oplossing van inflammasie en immuunselbalans.
14-HDHA (14-hidroksi-dokosaheksaensuur)	Dra by tot inflammasie-oplossing en bevorder sellulêre gesondheid.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie SPM ACTIVE® neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan voordat jy hierdie aanvulling neem. **Chirurgie:** SPM ACTIVE® kan die risiko van bloeding tydens en na die operasie verhoog. Hou op om SPM ACTIVE® ten minste 2 weke voor 'n geskeduleerde operasie te gebruik.

WAARSKUWING EN SPESIALE VOORSORGMAATREËLS

Indien jy enige van die volgende gedagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: bloedingsversteurings, lewersiekte, onbeheerde diabetes, hemorrhagiese beroerte. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Antikoagulant (bv. warfarin, aspirien), antiplaatjie medisyne en NSAID's (verhoogde risiko van bloeding), Antihypertensiewe medisyne (kan bloeddrukverlagende effekte verbeter), antikoagulant, immuunonderdrukkers (kan immuunrespons verander), statiene (potensieel additiewe lipiedverlagende effek). As enige van die volgende gebeur, hou op om SPM ACTIVE® te gebruik en vertel jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Allergiese reaksies- uitslag, Jeuk / swelling (veral van die gesig / tong / keel), erge duiseligheid, probleme met asemhaling;
- Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op SPM ACTIVE® gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê. Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):
- naarheid / braking, Ligte gastro-intestinale simptome (bv. spysvertering, windrigheid).

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op SPM ACTIVE® gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig.

Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het. Staak gebruik onmiddellik indien enige nadelige reaksie plaasvind. Lees hierdie inligtingsblad aandagtig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskrif.

- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie medisyne met enige ander persoon deel nie.
- Vra jou apteker of jy meer inligting of advies benodig.
- Jy moet 'n dokter raadpleeg indien jou toestand vererger of nie verbeter nie.

MOENIE HIERDIE PRODUK GEBRUIK NIE:

- As jy hipersensitief (allergies) is vir enige van die bestanddele wat gelys word.
- Jy moet nie hierdie produk aanvaar as seëls gebreek word nie.

NEWE-EFFEKTE

Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie medisyne, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad. As jy enige newe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE

BEHANDELING DAARVAN Sien newe-effekte.

Behandeling: Staak gebruik en raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

BERGING INSTRUKSIE

Bêre in 'n koel, donker plek, onder 25 °C.

Beskerm teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermende dop na elke gebruik.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie. Moenie SPM ACTIVE® gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE

Duidelike, ovaal, softgel kapsule met geel vulsel.

AANBIEDING

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksieseël, peuterkrimpseël, spons en silikagelsakkie.

REGISTRASIE NOMMER

Om by registrasie deur SAHPRA toegeken te word.

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

NAAM EN BESIGHEIDSADRES VAN APPLIKANT

Versprei deur:

Amipro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road,
Eastgate Extension, Sandton, 2146, Tel: 011- 802-8101

DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.