

## PATIENT INFORMATION LEAFLET

### 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

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU

- **SPM ACTIVE®** is available without a doctor's prescription.
- Nevertheless, you still need to use **SPM ACTIVE®** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **SPM ACTIVE®** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

#### WHAT IS IN THIS LEAFLET

- What **SPM ACTIVE®** is and what it is used for.
- What you need to know before you take **SPM ACTIVE®**.
- How to take **SPM ACTIVE®**.
- Possible side effects.
- How to store **SPM ACTIVE®**.
- Contents of the pack and other information.

#### WHAT SPM ACTIVE® CONTAINS

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)**

#### WHAT SPM ACTIVE® IS AND WHAT IT IS USED FOR

**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.

#### BEFORE YOU TAKE SPM ACTIVE®

If you are taking any chronic medication, do not use this product without consulting your healthcare provider. 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.

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

#### PREGNANCY AND BREASTFEEDING

Safety during pregnancy and breastfeeding has not been established, consult with your healthcare professional before use. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult with your healthcare professional before taking this supplement.

#### DRIVING AND USING MACHINES

It is not always possible to predict to what extent **SPM ACTIVE®** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities relating to requiring mental alertness, judgement and/or sound co-ordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until they are aware of the measure to which **SPM ACTIVE®** may affect you.

#### TAKING OTHER MEDICINES WITH SPM ACTIVE®

Complementary medicine products contain ingredients which may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your medical practitioner.



#### HOW TO TAKE SPM ACTIVE®

Do not share medicines prescribed for you with any other person. Always take **SPM ACTIVE®** exactly as described in this leaflet, or as your doctor, healthcare provider has instructed you. You should check with your doctor, pharmacist or healthcare provider if you are unsure.

#### 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.**

#### IF YOU TAKE MORE SPM ACTIVE® THAN YOU SHOULD

In the event of overdose, consult your doctor, pharmacist. Should none of these be available, contact the nearest hospital or poison control centre.

#### IF YOU FORGET TO TAKE SPM ACTIVE®

Do not take a double dose to make up for a missed dose.

#### POSSIBLE SIDE EFFECTS

**SPM ACTIVE®** may have side effects.

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 practitioner 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).

Not all side effects and interactions reported for **SPM ACTIVE®** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare professional.

#### REPORTING OF SIDE EFFECTS

If you experience side effects, talk to your doctor, pharmacist or other healthcare professional. You can also report side effects to SAHPRA via "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/index/8>. By reporting side effects, you can help provide more information on the safety of **SPM ACTIVE®**.

#### STORAGE AND DISPOSING OF SPM ACTIVE®

Store all medicines out of the reach of children.

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

Protect from direct sunlight and heat.

Store in the original packaging.

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

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

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

#### PRESENTATION OF SPM ACTIVE®

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

#### IDENTIFICATION OF SPM ACTIVE®

Clear, oval, softgel capsule with yellow fill.

#### REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

#### ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

#### THIS LEAFLET WAS LAST REVISED ON

02 January 2025.

#### NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

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



# PASIËNT INLIGTINGSBLAD

## SKEDULERINGSSTATUS S0

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.6 Vette, olies en vetsure

HANDELSNAAM EN DOSEERVORM,

## SPM ACTIVE®, 60 Kapsules

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

### BELANGRIKE INLIGTING VIR U

- **SPM ACTIVE®** is beskikbaar sonder doktersvoorskrif.
- U moet steeds **SPM ACTIVE®** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **SPM ACTIVE®** met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgpraktisyn of jy meer inligting of advies benodig.

### WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat **SPM ACTIVE®** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **SPM ACTIVE®** neem.
- Hoe om **SPM ACTIVE®** te neem.
- Moontlike nuwe-effekte.
- Hoe om **SPM ACTIVE®** te bêre.
- Inhoud van die pak en ander inligting

### WAT IS SPM ACTIVE® KAPSULES EN WAARVOOR WORD DIT GEBRUIK

**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.

### VOORDAT JY SPM ACTIVE® NEEM

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.

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

### BESTUUR EN GEBRUIK VAN MASIËNE

Dit is nie altyd moontlik om te voorspel in watter mate **SPM ACTIVE®** die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet seker maak dat hulle nie betrokke raak by aktiwiteite wat verband hou met die verlies van verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, ligging, seil, bedryfsmasjiene/toerusting, totdat hulle bewus is van die mate waartoe **SPM ACTIVE®** jou beïnvloed.

### WATER SPM ACTIVE® BEVAT

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

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, glierol, silika, tokoferolryke ekstrakte.

**Bevat:** Vis (ansjovis, sardien en makriel).

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

### NEEM VAN ANDER MEDISYNE SAAM MET SPM ACTIVE®

Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne 'n interaksie kan hê. As jy enige chroniese medisyne gebruik, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie.

### SWANGERSKAP EN BORVOEDING

Alhoewel veiligheid tydens swangerskap en borsvoeding vasgestel is, raadpleeg u gesondheidsorgpraktisyn voor gebruik. As u swanger is of borsvoed, dink dat u swanger is of beplan om 'n baba te hê, raadpleeg u gesondheidsorgpraktisyn voordat u hierdie aanvulling neem.

### HOE OM SPM ACTIVE® TE NEEM

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **SPM ACTIVE®** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, gesondheidsorgpraktisyn voorgeskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.

### Aanwysings vir gebruik:

**Volwasse:** Neem een (1) kapsule daaglik, of tot drie (3) per dag of soos voorgeskryf deur jou gesondheidspraktisyn.

**Moenie meer as die aanbevole dosis neem nie.**

**AS JY MEER SPM ACTIVE® NEEM AS WAT JY MOET**

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

**AS JY VERGEEFT OM SPM ACTIVE® TE NEEM**

Moenie 'n dubbele dosis neem om op te maak vir 'n dosis wat oorgeslaan is nie.

### MOONTLIKE NUWE-EFFEKTE

**SPM ACTIVE®** kan nuwe-effekte hê. Indien jy enige van die volgende diagnoseerde 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), anti-koagulant, immuunonderdrukkers (kan immuunrespons verander), statiene (potensiële additiewe lipiedverlagende effekte). As enige van die volgende gebeur, hou op om **SPM ACTIVE®** te gebruik en vertel jou dokter of gaan na die ongevallende 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 mag dalk dringende mediese hulp of hospitalisasie nodig hê.

Nuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteur aan u gesondheidsorgpraktisyn as dit voortduur):

- naarheid / braking, Ligte gastro-intestinale simptome (bv. spysvertering, winderigheid).

Nie alle nuwe-effekte en interaksies wat vir **SPM ACTIVE®** gerapporteer word, is by hierdie inligtingsblad gesluit nie. 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 nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

### AANMELDING VAN NUWE-EFFEKTE

As jy nuwe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook nuwe-effekte aan SAHPRa rapporteer via "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRa se publikasies:

<https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **SPM ACTIVE®**.

### HOE OM SPM ACTIVE® TE BÊRE

Bêre alle medisyne buite bereik van kinders.

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

Beskerm teen direkte sonlig en hitte.

Bêre in die oorspronklike verpakking.

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.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

### AANBIEDING VAN SPM ACTIVE®

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

### IDENTIFIKASIE VAN SPM ACTIVE®

Duidelike, ovaal, softgel kapsule met geel vulsel.

### REGISTRASIONOMMER

Om deur SAHPRa toegeken te word by registrasie.

### TOEGANG TOT DIE OORREKENBARE PROFESSIONELE INLIGTING

Skandeer QR-kode.

### HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP

02 Januarie 2025.

### NAAM EN ADRES VAN REGISTRASIEHOUDER

Versprei deur:

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

