

## PROFESSIONAL INFORMATION

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

**SCHEDULING STATUS:** S0

**1. NAME OF THE MEDICINE:** SPM ACTIVE

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Serving Size	2 softgels	
Servings Per Container: 60 pack size		30
Calories		10
Total Fat		1 g
Cholesterol		<5 mg
Active Fractionated Marine Lipid Concentrate [fish oil (anchovy, sardine, and mackerel) and mixed tocopherols (antioxidant)] SPM content standardized to 18-hydroxy-eicosapentaenoic acid (18-HEPE) and 17-hydroxy-docosahexaenoic acid (17-HDHA)		1 g

Other Ingredients: Softgel shell (gelatin, glycerin, and water), and silica. Contains: Fish (anchovy, sardine, and mackerel).

**For full list of excipients, see section 6.1**

This product is non-GMO and gluten-free.

**3. PHARMACEUTICAL FORM**

Clear, oval, light yellow to yellow, soft gelatin capsules.

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

**SPM Active** is designed to help support the body's natural capacity to respond to physical challenges and resolve the immune response. \*

\* This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. **SPM Active** does not intend to prevent or cure any form of illness or disease and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using this product.

**4.2 Posology and method of administration**

Take two softgels once daily or as directed by your healthcare practitioner

**4.3 Contraindications**

None known.

**4.4 Special warnings and precautions for use**

If pregnant, nursing, or taking nutritional supplements or medications, consult your healthcare practitioner before use. Keep out of the reach of children.

**4.5 Interaction with other medicines and other forms of interaction**

None known.

**4.6 Fertility, pregnancy and lactation**

If pregnant or nursing, consult your healthcare practitioner before use.

**4.7 Effects on ability to drive and use machines**

There are no adequate data from the use of **SPM Active** on the ability to drive and use machines.

**4.8 Undesirable effects**

None known.

**4.9 Overdose**

Treatment is symptomatic and supportive.

**5. PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

Category of medicine: D (Complementary Medicine)

Class of medicine: 34.13 Health supplements - Other

**5.2 Pharmacokinetic properties**

Pharmacokinetic studies have not been conducted on **SPM Active** product

**6. PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Silica  
Softgel shell:  
Gelatin  
Glycerin  
Water

**6.2 Incompatibilities**

None known.

**6.3 Shelf Life**

24 Months.

**6.4 Special precautions for storage**

Keep tightly closed in a cool, dry place  
Keep softgels in original container until required for use.  
KEEP OUT OF REACH OF CHILDREN.

**6.5 Nature and contents of container**

Packs of 60 softgels in PET bottle with PET lid  
Pack-size: 60 softgels.

**6.6 Special precautions for disposal**

No special requirements.

**7. HOLDER OF CERTIFICATE OF REGISTRATION**

Amipro Advanced Development Products (pty) Ltd  
Unit 3 Eastgate Business Park, 1 South Road, Marlboro, Sandton, Johannesburg 2063  
Tel: 011 802 8101

**8. REGISTRATION NUMBER**

Will be allocated by SAHPRA upon registration.

**9. DATE OF FIRST AUTHORISATION**

Will be allocated by SAHPRA upon registration.