

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: META-SITOSTEROL 2.0

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Serving Size	1 Tablet	
Servings Per Container:	90 pack size	90
Folate		445 mcg DFE
Beta-sitosterol		333 mg
Campesterol		167 mg
Stigmasterol		92 mg
Other Plant Sterols		117 mg

Other Ingredients: Plant sterol complex (soy), microcrystalline cellulose, croscarmellose sodium, cellulose, stearic acid (vegetable), silica, and calcium L-5-methyltetrahydrofolate. Contains: Soy.

For full list of excipients, see section 6.1

This product is gluten-free and vegetarian.

3. PHARMACEUTICAL FORM

Off white, speckled, uncoated tablet

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Meta-Sitosterol 2.0 is a naturally derived vegetable preparation featuring enhanced levels of a balanced concentrate of plant sterols—2 grams per day—which may help to maintain healthy blood cholesterol levels already within the normal range.*

* This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. **Meta-Sitosterol 2.0** 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 one tablet with each meal or as directed by your healthcare practitioner.

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

Please 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

There are no adequate data from the use of **Meta-Sitosterol 2.0** in pregnant or breast-feeding woman.

4.7 Effects on ability to drive and use machines

There are no adequate data from the use of **Meta-Sitosterol 2.0** 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 **Meta-Sitosterol 2.0** product

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Croscarmellose sodium
Cellulose
Stearic acid (vegetable)
Silica

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.

Do not refrigerate (Refrigeration may cause moisture condensation).

Keep tablets in original container until required for use.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Packs of 90 tablets in amber glass bottles

Pack-size: 90 tablets.

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.