

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: SPECTRAZYME COMPLETE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Serving Size 2 capsules
 Servings Per Container: 60 pack size 60

Proprietary Complete Enzyme Blend providing:	271 mg
Amylase 24 000 DU; Acid Protease 165 SAPU; Neutral Protease 20 000 PC; Xylanase 2 400 XU; Fungal Protease 4 100 HUT; Cellulase 2 000 CU; Lipase 800 FCCLU; Lactase 400 ALU; Pectinase 24 endo PGU; Hemicellulase 2 000 HCU; Invertase 480 SU.	

Other Ingredients: Capsule (hydroxypropylmethylcellulose), maltodextrin, and medium-chain triglycerides
 Contains: Milk, wheat, and soy.

For full list of excipients, see section 6.1

This product is non-GMO.

3. PHARMACEUTICAL FORM

White/cream-coloured capsules.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

SpectraZyme Complete provides digestive support with a non-GMO, broad spectrum of non-animal derived enzymes including acid stable lipase and three proteases that function in different pH ranges. This comprehensive enzyme complex is designed to support the healthy digestion of proteins, peptides, carbohydrates, fats, cellulose, maltose, lactose, and sucrose. *

* This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. **SpectraZyme Complete** 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 capsules with each meal or as directed by your healthcare practitioner.

4.3 Contraindications

None known.

4.4 Special warnings and precautions for use

If taking anti-diabetic medications, please 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

There are no adequate data from the use of **SpectraZyme Complete** 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 **SpectraZyme Complete** 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 **SpectraZyme Complete** product

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maltodextrin
 Medium-chain triglycerides
 Capsule:
 Hydroxypropylmethylcellulose

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 capsules in original container until required for use.
 KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

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

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.