

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 METAGEST

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Serving Size	2 tablets	
Servings Per Container:	90 pack size	45
Betaine HCl		1.3 g
Pepsin (porcine)		90 mg

Other Ingredients: Silicified microcrystalline cellulose, stearic acid (vegetable), cellulose, silica, magnesium stearate (vegetable), and coating (hypromellose, medium-chain triglycerides, and hydroxypropylcellulose).

For full list of excipients, see section 6.1

This product is non-GMO and gluten-free.

3. PHARMACEUTICAL FORM

White/off-white speckled, clear coated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

SpectraZyme Metagest features betaine HCl combined with pepsin—a proteolytic enzyme—to complement the natural production of digestive agents in the stomach. *

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4.2 Posology and method of administration

Take two tablets with each meal or as directed by your healthcare practitioner.

4.3 Contraindications

Do not use if there is a prior history of or a current peptic or duodenal ulcer.

4.4 Special warnings and precautions for use

If stomach discomfort occurs after administration, discontinue use and consult your healthcare practitioner. Consult your healthcare practitioner if pregnant or nursing, or if taking other nutritional supplements or medications. 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

Consult your healthcare practitioner if pregnant or nursing.

4.7 Effects on ability to drive and use machines

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Silicified microcrystalline cellulose
Stearic acid (vegetable)
Cellulose
Silica
Magnesium stearate (vegetable)
Tablet coating:
Hypromellose
Medium-chain triglycerides
Hydroxypropylcellulose

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 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 PET bottle with PET lid.
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.