



Metagenics® SpectraZyme Gluten Digest

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 GLUTEN DIGEST

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Serving Size	2 capsules	
Servings Per Container: 90 pack size		45
Prolyl Endopeptidase		276 mg
(from <i>Aspergillus niger</i>)		(232,000 PPI)

Other Ingredients: Microcrystalline cellulose, capsule (hydroxypropylmethylcellulose), stearic acid (vegetable), magnesium stearate (vegetable), and silica.

For full list of excipients, see section 6.1

This product is non-GMO, vegetarian, and gluten-free.

3. PHARMACEUTICAL FORM

White/cream-colored capsules.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

SpectraZyme Gluten Digest is an advanced gluten digestion support formula that contains Tolerase G, a non-animal-based enzyme that has been shown to effectively break down gluten*

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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 pregnant or nursing, or taking medication or other nutritional supplements, 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 Gluten Digest** 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 Gluten Digest** 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 Gluten Digest** product

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core:
Microcrystalline cellulose
Stearic acid (vegetable)
Magnesium stearate (vegetable)
Silica
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 90 capsules in amber glass bottles
Pack-size: 90 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.