

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 PAN 9X

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Serving Size	1 tablet	
Servings Per Container: 90 pack size		90
Pancreatin (porcine)		360 mg
Providing:		
Protease		67 500 USP units
Amylase		67 500 USP units
Lipase		10 200 USP units

Other Ingredients: Porcine pancreatic concentrate, microcrystalline cellulose, croscarmellose sodium, silica, and stearic acid (vegetable).

For full list of excipients, see section 6.1

This product is non-GMO and gluten-free.

3. PHARMACEUTICAL FORM

Light beige, mottled, uncoated tablets.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

SpectraZyme Pan 9x is a comprehensive enzyme complex that provides support for healthy digestive function. *

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4.2 Posology and method of administration

Take one tablet 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. Do not use in individuals who have a known allergy or hypersensitivity to pork protein.

4.4 Special warnings and precautions for use

Consult your healthcare practitioner 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

There are no adequate data from the use of **SpectraZyme Pan 9x** 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 Pan 9x** 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 Pan 9x** product

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Croscarmellose sodium
Silica
Stearic acid (vegetable)

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 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.