

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

34.5 Enzymes

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

SPECTRAZYME® PAN 9X, 90 Tablets

COMPOSITION

Each one (1) tablet of SPECTRAZYME® PAN 9X contains the following actives:

Pancreatin (porcine)	180 mg
Providing:	
Protease	33 750 USP units
Amylase	33 750 USP units
Lipase	5 100 USP units

Inactive Ingredients: Croscarmellose sodium, microcrystalline cellulose, silica, and stearic acid (vegetable).

This product is suitable for non-GMO, gluten & dairy free. (Sugar Free)

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

SPECTRAZYME® PAN 9X is a comprehensive enzyme complex that provides support for healthy digestive function. The porcine pancreatic concentrate is processed under special conditions so that the delicate enzyme constituents remain intact.

Ingredient	Use for Ingredient
Protease	Aids in the breakdown of proteins into amino acids for improved digestion and absorption.
Amylase	Assists in the breakdown of carbohydrates into simple sugars, supporting digestion and energy production.
Lipase	Helps break down fats into fatty acids and glycerol, enhancing fat digestion and nutrient absorption.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take SPECTRAZYME® PAN 9X if you are hypersensitive (allergic) to any of the ingredients. If you have allergies, be sure to check with your healthcare professional before taking this supplement.

WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: : peptic ulcer disease, gastroesophageal reflux disease (GERD) or irritable bowel syndrome (IBS), gallbladder disease. If you are taking the following medication, please consult with your healthcare professional before taking: oral diabetes medicine, medicines that reduce stomach acid. : medication that reduces stomach acid, antacids, diabetic medication. If any of the following happens, stop using SPECTRAZYME® PAN 9X and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions— rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing;



These are all very serious effects. If you have them, you may have had a serious reaction to SPECTRAZYME® PAN 9X. You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare professional if they continue):

- nausea/vomiting, constipation, loss of appetite, increased thirst, increased urination, mental/mood changes, unusual tiredness.

These are all very serious effects. If you have them, you may have had a serious reaction to SPECTRAZYME® PAN 9X. You may need urgent medical attention or hospitalisation.

Seek advice from a healthcare professional if you have any medical condition. Discontinue use immediately should any adverse reaction occur.

Read this leaflet carefully because it contains important information for you. This product is available without a doctor's prescription.

- Keep this leaflet. You may need to read it again.
- Do not share medication with any other person.
- Ask your pharmacist if you need more information or advice.
- You must consult a doctor should your condition worsen or does not improve.

DO NOT USE THIS PRODUCT:

- If you are hypersensitive (allergic) to any of the ingredients listed.
- Do not accept this package if seals are broken.

INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine. It is possible that exposure of certain supplement ingredients may interfere with certain medications. (See **Warnings & Special precautions**)

DOSAGE AND DIRECTIONS FOR USE

Adults: Take half a tablet (½) with each meal or as directed by your healthcare practitioner.

Do not take more than the recommended dose.

SIDE EFFECTS

Should your general health worsen, or if you experience any untoward effects while being exposed to this product, please consult your doctor, pharmacist or other healthcare professional for advice.

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

See side-effects.

Treatment:

Discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.

STORAGE INSTRUCTION

Store in a cool, dark place, below 25 °C.

Protect from direct sunlight and heat.

Store in the original bottle.

Keep the bottle tightly closed.

Replace the protective cap after each use.

Do not use after the expiry date stated on the bottle.

Do not use SPECTRAZYME® PAN 9X if you notice visible signs of deterioration.

IDENTIFICATION

Light beige, mottled, uncoated caplet.

PRESENTATION

A white 250 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

This medicine has not been evaluated by SAHPRA for quality, safety, or intended use.

NAME AND BUSINESS ADDRESS OF APPLICANT

Distributed by:

Ampiro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension,
Sandton, 2146
Tel: 011-802-8101

DATE OF PUBLICATION

To be allocated by the regulatory authority.

PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.5 Ensieme

HANDELSNAAM EN DOSEERVORM,

SPECTRAZYME® PAN 9X, 90 Tablette

SAMESTELING

Elke (1) tablet SPECTRAZYME® PAN 9X bevat die volgende aktiewe stowwe:

Pankreatien (vark)	180 mg
Voorsiening van:	
Protease	33 750 USP-eenhede
Amilase	33 750 USP-eenhede
Lipase	5 100 USP-eenhede

Onktiewe bestanddele: Croscarmellose-natrium, mikrokristallyne sellulose, silika en stearynsuur (groente).

Hierdie produk is geskik vir nie-GGO, gluten en suiwelvry. (Suikervry)

FARMAKOLOGIESE KLASIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

SPECTRAZYME® PAN 9X is 'n omvattende ensiemkompleks wat ondersteuning bied vir gesonde spysverteringsfunksie. Die varkpankreas-konsentraat word onder spesiale toestande verwerk sodat die delikate ensiembestanddele ongeskonde bly.

Bestanddeel	Gebruik vir bestanddeel
Protease	Help met die afbreek van proteïene in aminosure vir verbeterde vertering en absorpsie.
Amilase	Help met die afbreek van kooldhidrate in eenvoudige suikers, wat vertering en energieproduksie ondersteun.
Lipase	Help om vette in vetsure en gliserol af te breek, wat vertering en voedingstofabsorpsie verbeter.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **SPECTRAZYME® PAN 9X** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan voordat jy hierdie aanvulling neem.

WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: maagseriesekte, gastro-oesofageale refluxsiekte (GERD) of prikkelbare dermsindroom (IBS), galblaasiekte. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: medisyne wat maagsuur verminder, teenuurmiddels, diabetesie medisyne. As enige van die volgende gebeur, hou op om **SPECTRAZYME® PAN 9X** te gebruik en vertel jou dokter of gaan na die ongevale-afdeling by jou naaste hospitaal:

- Allergiese reaksie-uitslag, jeuk / swelling (veral van die gesig / tong / keel), erge duiseligheid, probleme met asemhaling.

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op **SPECTRAZYME® PAN 9X** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Nowe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):

- naarheid / braking, hardlywigheid, verlies aan eetlus, verhoogde dors, verhoogde urinering, geestelike / gemoedsveranderinge, ongewone moegheid.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **SPECTRAZYME® PAN 9X** gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig.

Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het. Staak gebruik onmiddellik indien enige nadelige reaksie plaasvind.

Lees hierdie inligtingsblad aandagtig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskrif.

- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie medisyne met enige ander persoon deel nie.
- Vra jou apteker of jy meer inligting of advies benodig.
- Jy moet 'n dokter raadpleeg indien jou toestand vererger of nie verbeter nie.

MOENIE HIERDIE PRODUK GEBRUIK NIE:

- As jy hipersensitief (allergies) is vir enige van die bestanddele wat gelys word.
- Jy moet nie hierdie produk aanvaar as seëls gebreek word nie.

INTERAKSIES

Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne gebruik. Dit is moontlik dat blootstelling van sekere

aanvullingsbestanddele met sekere medisyne 'n interaksie mag hê.

(Sien **Waarskuwings en Spesiale Voorsorgmaatreëls**)

DOSIS EN AANWYSINGS VIR GEBRUIK

Volwasse: Neem 'n halwe tablet (1/2) met elke maaltyd of soos voorgeskryf deur jou gesondheidspraktisyn.

Moenie meer as die aanbevole dosis neem nie.

NEWE-EFFEKTE

Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie medisyne, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Sien nuwe-effekte.

Behandeling:

Staak gebruik en raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

BERGING INSTRUKSIE

Bêre in 'n koel, donker plek, onder 25 °C.

Beskermt teen direkte sonlig en hitte.

Bêre n die oorspronklike bottel.

Hou die bottel styf toe.

Vervang die beskermende dop na elke gebruik.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie.

Moenie **SPECTRAZYME® PAN 9X** gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE

Ligte beige, gevlekte, onbedekte caplet.

AANBIEDING

'n Wit 250 ml HDPE-bottel met 'n wit dop, induksieseel, peuterkrimpseël, spons en silikagelsakke.

REGISTRASIE NOMMER

Om by registrasie deur SAHPRA toegeken te word.

Hierdie medisyne is nie deur SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

NAAM EN BESIGHEIDSADRES VAN APPLIKANT

Versprei deur:

Amipro Advanced Development Products (Pty) Ltd

Unit 3, Eastgate Business Park, 1 South Road,

Eastgate Extension,

Sandton, 2146,

Tel: 011- 802-8101

DATUM VAN PUBLIKASIE

Om deur die regulerende owerheid toegeken te word.