

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

34.5 Enzymes

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

SPECTRAZYME® COMPLETE, 60 Capsules

COMPOSITION

Each one (1) capsule of SPECTRAZYME® COMPLETE contains the following actives:

Proprietary Complete Enzyme Blend	271 mg
Providing:	
Amylase	24 000 FCC DU
Acid Protease	165 FCC SAP
Neutral Protease	20 000 FCC PC
Xylanase	2 400 FCC XU
Fungal Protease	4 100 FCC HUT
Cellulase	2 000 FCC CU
Lipase	800 FCC LU
Lactase	400 FCC ALU
Pectinase	24 FCC endo-PG
Hemicellulase	2 000 FCC HCU
Invertase	480 FCC SU

Inactive Ingredients: Capsule (hydroxypropyl methyl cellulose), maltodextrin, and medium-chain triglycerides. **Contains:** Milk, wheat, and soy. **Sugar Free.** This product is suitable for non-GMO.

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

SPECTRAZYME® COMPLETE contains a comprehensive blend of enzymes, formulated to support the digestion of a variety of components including proteins, carbohydrates, fats, cellulose, and lactose. This broad-spectrum enzyme complex includes acid-stable enzymes and multiple proteases, aiding digestion across different pH ranges.

Ingredient	Uses for Ingredient
Amylase	Breaks down starches into sugars, aiding carb digestion and reducing bloating.
Acid Protease	Breaks down proteins in the stomach, improving protein digestion and absorption.
Neutral Protease	Breaks down proteins in the small intestine, enhancing protein digestion.
Xylanase	Breaks down fibre from plant cell walls, improving digestion and reducing bloating.
Fungal Protease	Aids in breaking down proteins from fungi, helping with protein digestion.
Cellulase	Breaks down cellulose, helping digest plant-based foods and reducing bloating.
Lipase	Breaks down fats into fatty acids, aiding fat and fat-soluble vitamin absorption.
Lactase	Digests lactose in dairy, reducing symptoms of lactose intolerance.
Pectinase	Breaks down pectin, aiding fruit digestion and reducing discomfort from undigested fibre.
Hemicellulase	Breaks down hemicellulose, improving fibre digestion and gut health.
Invertase	Breaks down sucrose into glucose and fructose, supporting carb digestion.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take SPECTRAZYME® COMPLETE 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. **Antibiotics:** The active ingredients in SPECTRAZYME® COMPLETE may interact with antibiotics, take your antibiotics 2 hours before or 4 hours after taking SPECTRAZYME® COMPLETE. **Surgery:** Stop taking SPECTRAZYME® COMPLETE at least two weeks before scheduled surgery. **Laboratory tests:** Active ingredients in SPECTRAZYME® COMPLETE may alter the results of tests. Please tell your healthcare practitioner that you are taking SPECTRAZYME® COMPLETE before having any laboratory tests.

WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: History of digestive issues (ulcers), Pancreatitis, Autoimmune diseases. If you are taking the following medication, please consult with your healthcare professional before taking: Anticoagulants (Warfarin), Immunosuppressants, Antacids and proton pump inhibitors, Diabetes, Antibiotics (broad spectrum). If any of the following happens, stop using SPECTRAZYME® COMPLETE 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® COMPLETE. 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):

- Gastrointestinal discomfort, headache, nausea or vomiting. These are all very serious effects. If you have them, you may have had a serious reaction to SPECTRAZYME® COMPLETE. 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 two (2) capsules 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® COMPLETE if you notice visible signs of deterioration.

IDENTIFICATION

Cream vegetarian capsule, with a white to tan fill.

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:
Amipro 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® COMPLETE, 60 Kapsules

SAMESTELING

Elke (1) kapsules SPECTRAZYME® COMPLETE bevat die volgende aktiewe stowwe:

Eie volledige ensiemmengsel wat voorsien:	271 mg
Amilase	24 000 FCC DU
Suur Protease	165 FCC SAP
Neutrale protease	20 000 FCC-rekenaar
Xylanase	2 400 FCC XUL
Swam protease	4 100 FCC HUT
Sellulase	2 000 FCC CU
Lipase	800 FCC LU
Laktase	400 FCC ALU
Pektinas	24 FCC endo-PG
Hemisellulase	2 000 FCC HCU
Omkeer	480 FCC US

Onaktiewe bestanddele: Kapsule (hydroxypropylmethylcellulose), maltodextrine, en mediumketting trigliseriede.

Bevat: melk, koring en soja. Suikervry.

Hierdie produk is geskik vir nie-GGO.

FARMAKOLOGIESE KLASIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

SPECTRAZYME® COMPLETE bevat 'n omvattende mengsel van ensieme, geformuleer om die vertering van 'n verskeidenheid komponente te ondersteun, insluitend proteïene, koolhidrate, vette, sellulose en laktose. Hierdie breëspektrum ensiemkompleks sluit suurstabile ensieme en veelvuldige proteases in, wat vertering oor verskillende pH-reeke aanhelp.

Bestanddeel	Gebruik vir bestanddeel
Amilase	Breek stysels af in suikers, help koolhidraatvertering en verminder opgeblasenheid.
Suur Protease	Breek proteïene in die maag af, wat proteïenvertering en -absorpsie verbeter.
Neutrale protease	Breek proteïene in die dunderm af, wat proteïenvertering verbeter.
Xylanase	Breek vesel van plantselwande af, verbeter vertering en verminder opgeblasenheid.
Swam protease	Help met die afbreek van proteïene van swamme, wat help met proteïen vertering.
Sellulase	Breek sellulose af, help om plantaardige voedsel te verteer en opgeblasenheid te verminder.
Lipase	Breek vette af in vetsure, wat vet en vetoplosbare vitamienabsorpsie help.
Laktase	Verteer laktose in suiwel, wat simptome van laktose-intoleransie verminder.
Pektinas	Breek pektien af, help vrugtevertering en verminder ongemak van onverteerde vesel.
Hemisellulase	Breek hemisellulose af, verbeter veselvertering en dermgesondheid.
Omkeer	Breek sukrose af in glukose en frukose, wat koolhidraatvertering ondersteun.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **SPECTRAZYME® COMPLETE** 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. **Antibiotika:** Die aktiewe bestanddele in **SPECTRAZYME® COMPLETE** kan interaksie hê met antibiotika, neem jou antibiotika 2 ure voor of 4 ure nadat jy **SPECTRAZYME® COMPLETE** geneem het. **Chirurgie:** Hou op om **SPECTRAZYME® COMPLETE** ten minste twee weke voor die geskeduleerde operasie te neem. **Laboratoriumtoetse:** Aktiewe bestanddele in **SPECTRAZYME® COMPLETE** kan die resultate van toetse verander. Vertel asseblief jou gesondheidsorgpraktisyn dat jy **SPECTRAZYME® COMPLETE** neem voordat enige laboratoriumtoetse ondergaan word.

WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Indien jy enige van die volgende gedagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Geskiedenis van spysverteringsprobleme (maagsere), pankreatitis, outo-immun siektes. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy neem: Antikoagulant (Warfarin), Immuunonderdrukkers, Teensuurmiddels en protonpompremmers, Diabetes, Antibiotika (bree spektrum). As enige van die volgende gebeur, hou op om **SPECTRAZYME® COMPLETE** te gebruik en vertel jou dokter of gaan na die ongevalde-afdeling by jou naaste hospitaal:

- Allergiese reaksies-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® COMPLETE** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

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

- Gastro-intestinale ongemak, hoofpyn, naarheid of braking.
- Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **SPECTRAZYME® COMPLETE** 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 GEBUIK 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 voorsorgmatreëls**)

DOSIS EN AANWYSINGS VIR GEBUIK

Volwasse: Neem twee (2) kapsules 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 in 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® COMPLETE** gebruik as u sigbare tekens van agteruitgang opmerk nie.

INDENTIFIKASIE

Room vegetariese kapsule, met 'n bietjie bruin vul.

AANBEDIING

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

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.