

## PATIENT INFORMATION LEAFLET

### SCHEDULING STATUS <sup>50</sup>

Category D: Complementary medicine.

Discipline: Health Supplement

34.5 Enzymes

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

### SPECTRAZYME® COMPLETE, 60 Capsules

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS IMPORTANT INFORMATION FOR YOU

- **SPECTRAZYME® COMPLETE** is available without a doctor's prescription.
- Nevertheless, you still need to use **SPECTRAZYME® COMPLETE** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **SPECTRAZYME® COMPLETE** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

#### WHAT IS IN THIS LEAFLET

- What **SPECTRAZYME® COMPLETE** is and what it is used for.
- What you need to know before you take **SPECTRAZYME® COMPLETE**.
- How to take **SPECTRAZYME® COMPLETE**.
- Possible side effects.
- How to store **SPECTRAZYME® COMPLETE**.
- Contents of the pack and other information.

#### WHAT SPECTRAZYME® COMPLETE CONTAINS

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

Proprietary Complete Enzyme Blend Providing:	271 mg
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 (hydroxypropylmethylcellulose), maltodextrin, and medium-chain triglycerides. **Contains: Milk, wheat, and soy. Sugar Free. This product is suitable for non-GMO.**

#### WHAT SPECTRAZYME® COMPLETE IS AND WHAT IT IS USED FOR

**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.

#### BEFORE YOU TAKE SPECTRAZYME® COMPLETE

If you are taking any chronic medication, do not use this product without consulting your healthcare provider. 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.

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

#### PREGNANCY AND BREASTFEEDING

Although safety during pregnancy and breastfeeding has been established, consult with your healthcare professional before use. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult with your healthcare professional before taking this supplement.

#### DRIVING AND USING MACHINES

It is not always possible to predict to what extent **SPECTRAZYME® COMPLETE** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities relating to requiring mental alertness, judgement and/or sound co-ordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until they are aware of the measure to which **SPECTRAZYME® COMPLETE** may affect you. **TAKING OTHER MEDICINES WITH SPECTRAZYME® COMPLETE**

Complementary medicine products contain ingredients which may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your medical practitioner

#### HOW TO TAKE SPECTRAZYME® COMPLETE

Do not share medicines prescribed for you with any other person. Always take **SPECTRAZYME® COMPLETE** exactly as described in this leaflet, or as your doctor, healthcare provider has instructed you. You should check with your doctor, pharmacist or healthcare provider if you are unsure.

#### 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.**

#### IF YOU TAKE MORE SPECTRAZYME® COMPLETE THAN YOU SHOULD

In the event of overdose, consult your doctor, pharmacist. Should none of these be available, contact the nearest hospital or poison control centre.



#### IF YOU FORGET TO TAKE SPECTRAZYME® COMPLETE

Do not take a double dose to make up for a missed dose.

#### POSSIBLE SIDE EFFECTS

**SPECTRAZYME® COMPLETE** may have side effects.

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 practitioner 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.

Not all side effects and interactions reported for **SPECTRAZYME® COMPLETE** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare professional.

#### REPORTING OF SIDE EFFECTS

If you experience side effects, talk to your doctor, pharmacist or other healthcare professional. You can also report side effects to SAHPRA via "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **SPECTRAZYME® COMPLETE**.

#### STORAGE AND DISPOSING OF SPECTRAZYME® COMPLETE

Store all medicines out of the reach of children.

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

Protect from direct sunlight and heat.

Store in the original packaging.

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

Do not use **SPECTRAZYME® COMPLETE** if you notice visible signs of deterioration.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

#### PRESENTATION OF SPECTRAZYME® COMPLETE

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

#### IDENTIFICATION OF SPECTRAZYME® COMPLETE

Cream vegetarian capsule, with a white to tan fill.

#### REGISTRATION NUMBER –

To be allocated by SAHPRA upon registration.

#### ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

#### THIS LEAFLET WAS LAST REVISED ON

26 January 2025

#### NAME AND ADDRESS OF REGISTRATION HOLDER

**Distributed by:**

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# PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS **50**

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.5 Ensieme

HANDELSNAAM EN DOSEERVORM,

## SPECTRAZYME® COMPLETE, 60 Kapsule

LEES HIERDIE INLIGTINGSBLAD NOUKEURING, WANT DIT BEVAT BELANGRIKE

INLIGTING VIR U

- **SPECTRAZYME® COMPLETE** is beskikbaar sonder doktersvoorskrif.
- U moet steeds **SPECTRAZYME® COMPLETE** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **SPECTRAZYME® COMPLETE** met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgpraktisyn of jy meer inligting of advies benodig.

WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat **SPECTRAZYME® COMPLETE** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **SPECTRAZYME® COMPLETE** neem.
- Hoe om **SPECTRAZYME® COMPLETE** te neem.
- Moontlike newe-effekte.
- Hoe om **SPECTRAZYME® COMPLETE** te bêre.
- Inhoud van die pak en ander inligting

WATTER SPECTRAZYME® COMPLETE BEVAT

Elke een (1) kapsule SPECTRAZYME® COMPLETE bevat die volgende

aktiewe:

Eie volledige ensiemmengsel wat voorsien:	271 mg
Amlase	24 000 FCC DU
Suur Protease	165 FCC SAP
Neutrale protease	20 000 FCC-rekenaar
Xylanase	2 400 FCC XU
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.**

**WAT IS SPECTRAZYME® COMPLETE KAPSULES EN WAARVOOR WORD DIT GEBRUIK**

**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 suurstabiele ensieme en veelvuldige proteases in, wat vertering oor verskillende pH-reekse aanhelp.

**VOORDAT JY SPECTRAZYME® COMPLETE NEEM**

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. **Laboratoriumtoets:** Aktiewe bestanddele in **SPECTRAZYME® COMPLETE** kan die resultate van toets verander. Vertel asseblief jou gesondheidsorgpraktisyn dat jy **SPECTRAZYME® COMPLETE** neem voordat enige laboratoriumtoets ondergaan word.

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

**SWANGERSKAP EN BORSVOEDING**

Alhoewel veiligheid tydens swangerskap en borsvoeding vasgestel is, raadpleeg u gesondheidsorgpraktisyn voor gebruik. As u swanger is of borsvoed, dink dat u swanger is of beplan om 'n baba te hê, raadpleeg u gesondheidsorgpraktisyn voordat u hierdie aanvulling neem.

**BESTUUR EN GEBRUIK VAN MASIËNE**

Dit is nie altyd moontlik om te voorspel in watter mate **SPECTRAZYME® COMPLETE** die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet seker maak dat hulle nie betrokke raak by aktiwiteite wat verband hou met die vereiste van verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, seil, bedryfsmasjiene/toerusting, totdat hulle bewus is van die mate waartoe **SPECTRAZYME® COMPLETE** jou beïnvloed.

**NEEM VAN ANDER MEDISYNE SAAM MET SPECTRAZYME® COMPLETE**  
Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne 'n interaksie kan hê. As jy enige chroniese medisyne gebruik, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie.

**HOE OM SPECTRAZYME® COMPLETE TE NEEM**

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **SPECTRAZYME® COMPLETE** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, gesondheidsorgpraktisyn of voorskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.

**Aanwysings vir gebruik:**

**Volwasse:** Neem twee (2) kapsules met elke maaltyd of soos voorgeskryf deur u gesondheidsorgpraktisyn.

**Moenie meer as die aanbevole dosis neem nie.**

**AS JY MEER SPECTRAZYME® COMPLETE NEEM AS WAT JY MOET**

In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

**AS JY VERGEET OM SPECTRAZYME® COMPLETE TE NEEM**

Moenie 'n dubbele dosis neem om op te maak vir 'n dosis wat oorgeslaan is nie.

**MOONTLIKE NEWE-EFFEKTE**

**SPECTRAZYME® COMPLETE** kan newe-effekte hê.

Indien jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Geskiedenis van spysverteringsprobleme (maagsere), pankreatitis, outo-immun siektes.

As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: Antikoagulanse (Warfarin), Immunoonderdrukkers, Teensuurmiddels en protonpompremmers, Diabetes, Antibiotika (breë spektrum). As enige van die volgende gebeur, hou op om **SPECTRAZYME® COMPLETE** te gebruik en vertel jou dokter of gaan na die ongevalle-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 mag dalk dringende mediese hulp of hospitalisasie nodig hê.

Newe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan u gesondheidsorgpraktisyn as dit voortduur):

- Gastro-intestinale ongemak, hoofpyn, naderheid of braking.

Nie alle newe-effekte en interaksies wat vir **SPECTRAZYME® COMPLETE** gerapporteer word, is by hierdie inligtingsblad ingesluit nie. 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 newe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

**AANMELDING VAN NEWE-EFFEKTE**

As jy newe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook newe-effekte aan SAHPRa rapporteer via "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRa se publikasies:

<https://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **SPECTRAZYME® COMPLETE**.

**HOE OM SPECTRAZYME® COMPLETE TE BÊRE**

Bêre alle medisyne buite bereik van kinders.

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

Beskerm teen direkte sonlig en hitte.

Bêre in die oorspronklike verpakking.

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.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

**AANBIEDING VAN SPECTRAZYME® COMPLETE**

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

**IDENTIFIKASIE VAN SPECTRAZYME® COMPLETE**

Room vegetariese kapsule, met 'n bietjie bruin wul.

**REGISTRASIONOMMER**

Om deur SAHPRa toegesien te word by registrasie.

**TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING**

Skandeer QR-kode.

**HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP**

26 Januarie 2025

**NAAM EN ADRES VAN REGISTRASIEHOUER**

Versprei deur:

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