

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

34.12 Multiple Substance Formulation

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

SPECTRAZYME® METAGEST, 90 Tablets

COMPOSITION

Each one (1) tablet of SPECTRAZYME® METAGEST contains the following actives:

Betaine HCl	650 mg
Pepsin (porcine)	450 000 FCC
	Pepsin units

Inactive Ingredients: Silicified microcrystalline cellulose, stearic acid (vegetable), cellulose, silica, magnesium stearate (vegetable), and coating (hypromellose, medium-chain triglycerides, and hydroxypropylcellulose).
This product is suitable for non-GMO, gluten & dairy free.

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

SPECTRAZYME® METAGEST features betaine HCl combined with pepsin—a proteolytic enzyme—to complement the natural production of digestive proteins and enzymes in the stomach.

Ingredients	Uses for ingredient
Betaine HCl	Betaine hydrochloride is recommended by some doctors as a supplemental source of hydrochloric acid for people who have a deficiency of stomach acid production (hypochlorhydria).
Pepsin (porcine)	Pepsin is a stomach enzyme that serves to digest proteins found in ingested food.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take SPECTRAZYME® METAGEST 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® METAGEST 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® METAGEST. 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® METAGEST. 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: Chew or swallow one (1) tablet daily with food 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® METAGEST if you notice visible signs of deterioration.

IDENTIFICATION

White/off white, speckled, coated 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:

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.

Disipliene: Gesondheidsaanvulling

34.12 Meervoudige Bestanddeel Formulasie

HANDELSNAAM EN DOSEERVORM,

SPECTRAZYME® METAGEST, 90 Tablette

SAMESTELING

Elke (1) tablet SPECTRAZYME® METAGEST bevat die volgende aktiewe

stowwre:

Betaïen HCl	650 mg
Pepsien (varkbros)	450 000 FCC
	Pepsien-eenheids

Onaktiewe bestanddele: Gesilikonêerde mikrokristallyne sellulose, steariensuur (plant), sellulose, silika, magnesiumstearaat (plant), en bedekking (hipromellose, mediumketting triglisieriede, en hidrosipropielsellulose).

Hierdie produk is geskik vir nie-GMO, gluten en suiwelvr.

FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

SPECTRAZYME® METAGEST bevat betaïen HCl gekombineer met pepsien—'n proteolitiese ensiem—om die natuurlike produksie van verteringsproteïene en -ensieme in die maag aan te vul.

Bestanddele	Gebuike vir bestanddeel
Betaïen HCl	Betaïnhidrochloried word deur sommige dokters aanbeveel as 'n aanvullende bron van soutsuur vir mense wat 'n tekort aan maagsuurproduksie (hipochloorhidrie) het.
Pepsien (l)	Pepsien is 'n maagsiem wat dien om proteïene wat in ingeneemde voedsel voorkom, te verteer.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **SPECTRAZYME® METAGEST** 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 vir gebuik: maagseriese, gastro-oesofageale refluxsiekte (GERD) of prikkelbare dermsindroom (IBS), galblaassiekte. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy neem: medisyne wat maagsuur vermind, teensuurmiddels, diabetiese medisyne. As enige van die volgende gebeur, hou op om **SPECTRAZYME® METAGEST** te gebruik en vertel jou dokter of gaan na die ongevale-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® METAGEST** 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):

- 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® METAGEST** 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**)

DISOS EN AANWYINGS VIR GEBRUIK

Volwasse: Kou of sluk daaglik een (1) tablet saam met kos of soos voorgeskryf deur jou gesondheidsorgpraktisyn.

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.

Beskerms 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® METAGEST** gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE

Wit/spierwit, gespikkelde, bedekte 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 BESIGHEIDSAADRES VAN APPLICANT

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.