

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

DIGESTIZYME, 60 & 120 Capsules

COMPOSITION

Each one (1) capsule of DIGESTIZYME contains the following actives:

Bromelain	250 000 FCC PU
Protease 4.5	7000 FCC HUT
Amylase	4000 FCC DU
Peptidase	2250 FCC HUT
Lactase	400 FCC ALU
Cellulase	300 FCC CU
Alpha Galactosidase	295 FCC GaLU
Invertase	200 FCC SU
Diastase	245 FCC DP
Lipase	100 FCC LU
Glucoamylase	10 FCC AGU
Phytase	6 FCC FTU
Fenugreek (seed)	80 mg
Papaya (leaf)	75 mg
Fennel (seed)	20 mg
Peppermint (leaf)	20 mg
Ginger (rhizome)	15 mg
Parsley (leaf)	10 mg

Inactive Ingredients: Soybean oil powder, vegetarian capsule.

This product is dairy free. (Sugar Free)

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

DIGESTIZYME is a comprehensive enzyme complex that provides support for healthy digestive function. An advanced plant based enzyme formula containing a complete blend of enzymes and co-factors needed for the digestion and assimilation of an average sized meal containing protein, fats, carbohydrates, fibre and dairy products.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **DIGESTIZYME** 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.

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)

DOSEAGE AND DIRECTIONS FOR USE

Adults: Take one (1) to two (2) capsules daily with meals or as directed by your healthcare practitioner. Do not take more than the recommended dose.

Ingredients	Uses for ingredient
Bromelain	Aids in protein digestion and reduces inflammation.
Protease 4.5	Breaks down proteins into amino acids for improved digestion.
Amylase	Assists in breaking down carbohydrates into simple sugars.
Peptidase	Supports digestion by breaking down peptides into smaller amino acids.
Lactase	Helps digest lactose in dairy products, reducing lactose intolerance symptoms.
Cellulase	Breaks down cellulose in plant fibre for better nutrient absorption.
Alpha Galactosidase	Reduces gas and bloating by breaking down complex carbohydrates.
Invertase	Converts sucrose into glucose and fructose for easier digestion.
Diastase	Breaks down starches into simpler sugars for energy.
Lipase	Facilitates the digestion of fats into fatty acids and glycerol.
Glucoamylase	Converts starch into glucose for energy production.
Phytase	Improves mineral absorption by breaking down phytic acid in plant-based foods.
Fenugreek (seed)	Promotes digestion, balances blood sugar, and supports lactation.
Papaya (leaf)	Aids digestion, reduces inflammation, and supports immune health.
Fennel (seed)	Eases bloating, supports digestion, and alleviates menstrual cramps.
Peppermint (leaf)	Relieves indigestion, soothes the stomach, and reduces bloating.
Ginger (rhizome)	Eases nausea, reduces inflammation, and supports digestive health.
Parsley (leaf)	Acts as a natural diuretic, promotes kidney health, and aids digestion.



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.

WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: bleeding disorders, peptic ulcers or gastrointestinal inflammation, galactosemia (a genetic disorder that affects galactose metabolism), pancreatitis or other pancreatic disorders, hormone-sensitive conditions (e.g., breast cancer, uterine cancer, endometriosis), diabetes, individuals with GERD (gastroesophageal reflux disease) or hiatal hernia, gallbladder issues or bile duct obstruction, gallstone disease, kidney disease. If you are taking the following medication, please consult with your healthcare professional before taking: anticoagulants (e.g., warfarin), antiplatelet medication, blood sugar-lowering medication. **DIGESTIZYME** may increase your sensitivity to sunlight (photosensitivity). If any of the following happens, stop using DIGESTIZYME 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 **DIGESTIZYME**. 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, flatulence.
- These are all very serious effects. If you have them, you may have had a serious reaction to **DIGESTIZYME**. 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.
- Read 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.

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 **DIGESTIZYME** if you notice visible signs of deterioration.

IDENTIFICATION –

Vegetable capsule.

PRESENTATION

60 CAPSULES: A white 175 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

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

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.

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:

Ampro 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: Dissiplinespesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

DIGESTIZYME, 60 & 120 Kapsules

SAMESTELING

Elke een (1) kapsule DIGESTIZYME bevat die volgende aktiewe stowwe:

Bromelain	250 000 FCC PU
Protease 4.5	7000 FCC HUT
Amilase	4000 FCC DU
Peptidase	2250 FCC HUT
Laktase	400 FCC ALLU
Sellulase	300 FCC CUJ
Alfa Galaktosidase	295 FCC GalU
Omkeer	200 FCC US
Diastase	245 FCC DP
Lipase	100 FCC LUJ
Glukoamilase	100 FCC AGU
Fitase	6 FCC FTU
Fenegriek (saad)	80 mg
Papaja (blaar)	75 mg
Vinkel (saad)	20 mg
Peperment (blaar)	20 mg
Gemmer (risoom)	15 mg
Pietersielie (blaar)	10 mg

Naktiewe bestanddele: Sojaboonoliepoelie, vegetariese kapsule.

Hierdie produk is suiwerly. (Suikerervy)

FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

DIGESTIZYME is 'n omvattende ensiemkompleks wat ondersteuning bied vir gesonde spysverteringsfunksie. 'n Gevorderde plantgebaseerde ensiemformule wat 'n volledige mengsel van ensieme en ko-faktore bevat wat noodig is vir die vertering en assimilasie van 'n gemiddelde grootte maag wat proteiene, vette, koolhidrate, vesel en suiwelprodukte bevat.

Bestanddele	Gebruik vir bestanddeel
Bromelain	Help met proteïen vertering en verminder inflammasie.
Protease 4.5	Breek proteïene af in aminosure vir verbeterde vertering.
Amilase	Help met die afbreek van koolhidrate in eenvoudige suikers.
Peptidase	Ondersteun vertering deur peptiede in kleiner aminosure af te breek.
Laktase	Help om laktose in suiwelprodukte te verteer, wat laktose-intoleransie simptome verminder.
Sellulase	Breek sellulose in plantvesel af vir beter voedingstofabsorpsie.
Alfa Galaktosidase	Verminder gas en opgeblasenheid deur komplekse koolhidrate af te breek.
Omkeer	Onskep suikrose in glukose en fruktose vir makliker vertering.
Diastase	Breek stysel af in eenvoudige suikers vir energie.
Lipase	Faciliteer die vertering van vette in vetsure en gliserol.
Glukoamilase	Skakel stysel om in glukose vir energieproduksie.
Fitase	Verbeter minerale absorpsie deur fitiensuur in plantgebaseerde voedsel af te breek.
Fenegriek (saad)	Bevorder spysvertering, balanseer bloedsuiker en ondersteun laktasie.
Papaja (blaar)	Help vertering, verminder inflammasie en ondersteun immunogsondheid.
Vinkel (saad)	Vergemaklik opgeblasenheid, ondersteun spysvertering en verlig menstruele krampe.
Peperment (blaar)	Verlig spysvertering, streel die maag en verminder opgeblasenheid.
Gemmer (risoom)	Verlig naarheid, verminder inflammasie en ondersteun spysverteringstelselgesondheid.
Pietersielie (blaar)	Dien as 'n natuurlike diuretikum, bevorder niergesondheid en help vertering.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **DIGESTIZYME** 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.

INTERAKSIE

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**)

DOSES EN AANWYSINGS VIR GEBRUIK

Volwassene: Neem daagliks een (1) tot twee (2) kapsules saam met etes of soos voorgeskryf deur jou gesondheidspraktisyn.

Moenie meer as die aanbevole dosis neem nie.

WAARSKUWING EN SPESIALE VOORSORGMATREËLS

Indien jy enige van die volgende gedagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: bloedingsversteurings, maagere of galakto-inflammasie, galaktosemie ('n genetiese afwyking wat galaktosemetabolisme beïnvloed), pankreatitis of ander pankreasafwykings, hormoonensiweltoestande (bv. borskanker, baarmoederkanker, endometriose), diabetes, individu met GERD (gastro-oesofageale refluksiekte) of hiatale breuk, galblaasprobleme of galblus obstruksie, galsteensiekte, niersiekte. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: antikoagulant (bv. warfarin), antiplaatjie medisyne, bloedsuikerverlagende medisyne. **DIGESTIZYME** kan jou sensitiwiteit vir sonlig (fotosensitiwiteit) verhoog. As enige van die volgende gebeur, hou op om **DIGESTIZYME** 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 **DIGESTIZYME** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê. Nuwe-efekte wat gewoonlik nie mediese hulp benodig nie (rapporteur aan jou gesondheidsorgpraktisyn as hulle voortduur):

- naarheid / braking, widerigheid.

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op **DIGESTIZYME** 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.

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-efekte 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-efekte.

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

BERGING INSTRUKSIE

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

Beskerm 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 **DIGESTIZYME** gebruik as u sigbare tekens van agteruitgang opmerk nie.

IDENTIFIKASIE

Groentekapsule.

AANBIEDING

60 KAPSULES: 'n Wit 175 ml HDPE-bottel met 'n wit dop, induksiesêl, peuterkrimpseël, spons en siikagelsakkie.

120 KAPSULES: 'n Wit 250 ml HDPE-bottel met 'n wit dop, induksiesêl, peuterkrimpseël, spons en siikagelsakkie.

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 BESIGHEIDSDRES 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.