

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

DIGESTIZYME, 60 & 120 Capsules

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

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

WHAT IS IN THIS LEAFLET

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

WHAT DIGESTIZYME CONTAINS

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)

WHAT DIGESTIZYME IS AND WHAT IT IS USED FOR

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.

BEFORE YOU TAKE DIGESTIZYME

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

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

PREGNANCY AND BREASTFEEDING

Safety during pregnancy and breastfeeding has not 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 **DIGESTIZYME** 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 **DIGESTIZYME** may affect you.

TAKING OTHER MEDICINES WITH DIGESTIZYME

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 DIGESTIZYME

Do not share medicines prescribed for you with any other person. Always take **DIGESTIZYME** 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 one (1) to two (2) capsules daily with meals or as directed by your healthcare practitioner.

Do not take more than the recommended dose.

IF YOU TAKE MORE DIGESTIZYME 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 DIGESTIZYME

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

POSSIBLE SIDE EFFECTS

DIGESTIZYME may have side effects.

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 practitioner 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.

Not all side effects and interactions reported for **DIGESTIZYME** 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 **DIGESTIZYME**.

STORAGE AND DISPOSING OF DIGESTIZYME

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

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

PRESENTATION OF DIGESTIZYME

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.

IDENTIFICATION OF DIGESTIZYME

Vegetable capsule.

REGISTRATION NUMBER –

To be allocated by SAHPRA upon registration.

ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

THIS LEAFLET WAS LAST REVISED ON

19 December 2024

NAME AND ADDRESS OF REGISTRATION HOLDER

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PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS ⁵⁰

Kategorie D: Komplementêre medisyne.

Dissipline: Dissiplinespesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

DIGESTIZYME, 60 & 120 Kapsules

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

BELANGRIKE INLIGTING VIR U

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

WAT IS IN HIERDIE INLIGTINGSBLAD

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

WATTER DIGESTIZYME BEVAT

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

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

Onaktiewe bestanddele: Sojaboonoliepoei, vegetariese kapsule.

Hierdie produk is suiwelvry. (Suikevry)

WAT IS DIGESTIZYME KAPSULES EN WAARVOOR WORD DIT GEBRUIK

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

VOORDAT JY DIGESTIZYME NEEM

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.

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

BESTUUR EN GEBRUIK VAN MASJINE

Dit is nie altyd moontlik om te voorspel in watter mate **DIGESTIZYME** 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, bedryfsmasjien/toerusting, totdat hulle bewus is van die mate waartoe **DIGESTIZYME** jou beïnvloed.

NEEM VAN ANDER MEDISYNE SAAM MET DIGESTIZYME

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.

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 bieram om 'n baba te hê, raadpleeg u gesondheidsorgpraktisyn voordat u hierdie aanvulling neem.

HOE OM DIGESTIZYME TE NEEM

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

Aanwysings vir gebruik:

Volwassenes: Neem daaglik een (1) tot twee (2) kapsules saam met etes of soos voorgeskryf deur jou gesondheidsorgpraktisyn.

Moenie meer as die aanbevole dosis neem nie.

AS JY MEER DIGESTIZYME 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 DIGESTIZYME TE NEEM

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

MOONTLIKE NUWE-EFFEKTE

DIGESTIZYME kan nuwe-effekte hê.

Indien jy enige van die volgende diagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: :
bloedingsversteurings, maagere of gastro-inflammasie, galaktosemie ('n genetiese afwyking wat galaktosemetabolisme beïnvloed), pankreatitis of ander pankreasafwykings, hormoonsensitiewe toestande (bv. borskanker, baarmoederkanker, endometriose), diabetes, individue met GERD (gastro-oesofageale refluksiekte) of hiatale breuk, galblaasprobleme of galbus obstruksie, galsteensiekte, niersiekte. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem:
antikoagulanse (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 mag dalk dringende mediese hulp of hospitalisasie nodig hê.

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

- naarheid / braking, wonderigheid.

Nie alle nuwe-effekte en interaksies wat vir **DIGESTIZYME** 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 nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

AANMELDING VAN NUWE-EFFEKTE

As jy nuwe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook nuwe-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 nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **DIGESTIZYME**.

HOE OM DIGESTIZYME TE BÊRE

Bêre alle medisyne buite bereik van kinders.

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

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

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

AANBIEDING VAN DIGESTIZYME

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

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

IDENTIFIKASIE VAN DIGESTIZYME

Groentekapsule.

REGISTRASIE NOMMER

Om deur SAHPRA toegeken te word by registrasie.

TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING

Skandeer QR-kode.

HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP

19 Desember 2024

NAAM EN ADRES VAN REGISTRASIEHOUER

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