

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS ⁵⁰

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM –

COLON ECOLOGY, 70 & 150 Capsules

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

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

WHAT IS IN THIS LEAFLET

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

WHAT COLON ECOLOGY CONTAINS

Each one (1) capsules of **COLON ECOLOGY** contains the following actives:

Lactobacillus Sporogenes	198 Million CFU
Psyllium Seed Husk Powder	400 mg
Slippery Elm (Ulmus rubra) bark	125 mg
Barley Grass (Hordeum vulgare) powder	100 mg
Oat Bran (Avena sativa) powder	50 mg
Carrot (Daucus carota) powder	50 mg
FOS (Fructooligosaccharides)	25 mg
Vitamin C (as Calcium ascorbate)	25 mg
Flaxseed (Linum usitatissimum) powder	25 mg
Aloe Vera (Aloe Vera) [Leaf 200:1 extract]	12,5 mg
Prune (Prunus domestica) powder	12,5 mg
Digeyme®	5 mg
Vitamin H (as biotin)	200 µg

Inactive Ingredients: Magnesium stearate, modified cellulose, purified water (capsule shell), rice flour.

This product is suitable for non-GMO and vegetarian (Sugar Free)

WHAT COLON ECOLOGY IS AND WHAT IT IS USED FOR

COLON ECOLOGY helps alleviate wind and bloating and promotes bowel regularity. Colon Ecology is a proprietary blend of high-quality soluble and insoluble fibre, herbal concentrates, enzymes and beneficial probiotics.

BEFORE YOU TAKE COLON ECOLOGY

If you are taking any chronic medication, do not use this product without consulting your healthcare provider. Do not take **COLON ECOLOGY** 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. **Surgery:** **COLON ECOLOGY** might increase the risk of bleeding during and after surgery. Stop using **COLON ECOLOGY** at least 2 weeks before a scheduled surgery.

Laboratory tests: Taking biotin supplements might interfere with the results of many different blood lab tests. Biotin can cause falsely high or falsely low test results. This might lead to missed or incorrect diagnoses. Tell your doctor if you are taking biotin supplements, especially if you are having lab tests done.

Antibiotics: Take your antibiotics 2 hours before or after taking **COLON ECOLOGY**.

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 tell to what extent **COLON ECOLOGY** 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 **COLON ECOLOGY** may affect you.

TAKING OTHER MEDICINES WITH COLON ECOLOGY

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.

Document Reference: COLONE.PIL.CMP 12-24



HOW TO TAKE COLON ECOLOGY

Do not share medicines prescribed for you with any other person. Always take **COLON ECOLOGY** 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 daily on an empty stomach with an extra glass of water or as directed by your healthcare practitioner. **Do not take more than the recommended dose.**

IF YOU TAKE MORE COLON ECOLOGY 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 COLON ECOLOGY

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

POSSIBLE SIDE EFFECTS

COLON ECOLOGY may have side effects.

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: immunocompromised patients and in patients with gastrointestinal perforations, inflammatory bowel disease, Phenylketonuria, Stomach or intestine problems, Celiac disease or gluten sensitivity, Allergies to cereal grains, Disorders of the digestive tract including the esophagus, stomach, and intestines, Hormone-sensitive cancers or conditions, High triglyceride levels (hypertriglyceridemia), Intestinal conditions such as Crohn disease, ulcerative colitis, or obstruction, Kidney problems, An inherited condition in which the body cannot process biotin (biotinidase deficiency), Kidney dialysis. If you are taking the following medication, please consult with your healthcare practitioner before taking: Insulin, diabetes (Antidiabetes drugs), quinolone antibiotics (such as ciprofloxacin, levofloxacin), tetracycline antibiotics (such as doxycycline, minocycline), thyroid medications (such as levothyroxine), and drugs for osteoporosis (bisphosphonates such as alendronate), slow blood clotting (Anticoagulant / Antiplatelet drugs), Oestrogens, high blood pressure (Antihypertensive drugs), Digoxin (Lanoxin), Stimulant laxatives, Warfarin (Coumadin), Water pills (Diuretic drugs). If any of the following happens, stop using **COLON ECOLOGY** 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 **COLON ECOLOGY**. 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 **COLON ECOLOGY** 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 **COLON ECOLOGY**.

STORAGE AND DISPOSING OF COLON ECOLOGY

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 **COLON ECOLOGY** if you notice visible signs of deterioration. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF COLON ECOLOGY

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

150 CAPSULES: A white 375 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

IDENTIFICATION OF COLON ECOLOGY

Clear, 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 S0

Kategorie D: Komplementêre medisyne.

Dissipline: Dissiplinespesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

COLON ECOLOGY, 70 & 150 Kapsules

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

BLANGRIKE INLIGTING VIR U

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

WAT IS IN HIERDIE INLIGTINGSBLAD

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

WATTER COLON ECOLOGY BEVAT

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

Lactobacillus Sporogenes	198 Miljoen CFU
Psyllium Saad Skil Poerier	400 mg
Gladde Elm (<i>Ulmus rubra</i>) Bas	125 mg
Garsgras (<i>Hordeum vulgare</i>) poerier	100 mg
Hawersmelles (<i>Avena sativa</i>) poerier	50 mg
Wortel (<i>Daucus carota</i>) poerier	50 mg
FOS (Fructooligosakkariede)	25 mg
Vitamien C (as kalsiumskorbaat)	25 mg
Vlasaad (<i>Linum usitatissimum</i>) poerier	25 mg
Aloe Vera (<i>Aloe Vera</i>) [Blaar 200-1 uittreksel]	12,5 mg
Snoei (<i>Prunus domestica</i>) poerier	12,5 mg
Digeyzme [®]	5 mg
Vitamien H (as biotien)	200 µg

Onaktiewe bestanddele: Magnesiumstearaat, gemodifiseerde sellulose, gesuiwer water (kapsulodop), rysmeel.

Hierdie produk is geskik vir nie-GGO en vegetariër (suikervry)

WAT IS COLON ECOLOGY KAPSULES EN WAARVOOR WORD DIT GEBRUIK
COLON ECOLOGY help om wind en opgeblasenheid te verlig en bevorder dermgereetheid. **COLON ECOLOGY** is 'n nie mengsel van hoë kwaliteit oplosbare en onoplosbare vesel, kruiekonsetrate, en hoë voordeelige probiotika.

VOORDAT JY COLON ECOLOGY NEEM

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisy te raadpleeg nie. Moenie **COLON ECOLOGY** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisy gaan voordat jy hierdie aanvulling neem.

Chirurgie: **COLON ECOLOGY** kan die risiko van bloeding tydens en na die operasie verhoog. Hou op om **COLON ECOLOGY** ten minste 2 weke voor 'n geskeduleerde operasie te gebruik. **Laboratoriumtoets:**

Biottenaanvullings kan inmeng met die resultate van baie verskillende bloedlaboratoriumtoets. Biotien kan vals hoë of vals lae toetsresultate veroorsaak. Dit kan lei tot gemiste of verkeerde diagnoses. Vertel jou dokter as jy biottenaanvullings neem, veral as jy laboratoriumtoets laat doen. **Antibiotika:** Neem jou antibiotika 2 ure voor of na die neem van **COLON ECOLOGY**.

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

BESTUUR EN GEBRUIK VAN MASIJEENE

Dit is nie altyd moontlik om te voorspel in watter mate **COLON ECOLOGY** 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 **COLON ECOLOGY** jou beïnvloed.

NEEM VAN ANDER MEDISYNE SAAM MET COLON ECOLOGY

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 gesondheidsorgpraktisy te raadpleeg nie.

SWANERSKAP EN BORSVOEDING

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

HOE OM COLON ECOLOGY TE NEEM

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

Aanwysings vir gebruik:

Volwassenes: Neem daaglik twee (2) kapsules op 'n leë maag met 'n ekstra glas water of soos voorskryf deur jou gesondheidsorgpraktisy.

Moenie meer as die aanbevole dosis neem nie.

AS JY MEER COLON ECOLOGY 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 VERGETE OM COLON ECOLOGY TE NEEM

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

MOONTLIKE NUWE-EFFEKTE

COLON ECOLOGY kan nuwe-effekte hê.

Indien jy enige van die volgende gedagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisy voor gebruik: bloedingsversteurings, hartsielktes, diabetes, kop- en nekanker, swak en bros bene (osteoporose), prostaatanker, 'n oorgeërfde oogtoestand wat swak nagsig en verlies aan syvisie (retinitis pigmentosa) veroorsaak, beroerte, lewersiekte, post-chirurgiese stentplasing, Gewigsverlieschirurgie, prosedures om vernoude are (angioplastie) te verbreed, beslagelingsversteuring. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktisy voordat jy neem: medisyne vir kanker (Chemoterapie), bloedstolling (Antikoagulant / Antiplaatjiedmiddels), Warfarin (Coumadin), Antibiotika vir kanker (Antitumor Antibiotika), Antibiotika (Tetraskilien antibiotika), Amiodarone (Cardarone), Fenobarbital (Luminal), medisyne vir hoë bloeddruk (antihypertensiewe middels), 5-Fluorouracil, medisyne vir diabetes (Antidiabetes dwelms). As enige van die volgende gebeur, hou op om **COLON ECOLOGY** 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 **COLON ECOLOGY** gehad. Jy mag dalk dringende mediese hulp of hospitalisasie nodig hê.

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

- naarheid / braking, wonderigheid.

Nie alle nuwe-effekte en interaksies wat vir **COLON ECOLOGY**

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 gesondheidsorgpraktisy vir raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisy in kennis.

AANMELDING VAN NUWE-EFFEKTE

As jy nuwe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisy. 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 **COLON ECOLOGY**.

HOE OM COLON ECOLOGY TE BÊRÊ

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 **COLON ECOLOGY** gebruik as u sigbare tekens van agteruitgang opmerk nie.

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

AANBIEDING VAN COLON ECOLOGY

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

150 KAPSULES: 'n Wit 375 ml HDPE-bottel met 'n wit dop, induksieseël, peuterkrimpseël, spons en slikgagsakke.

IDENTIFIKASIE VAN COLON ECOLOGY

Duidelike, groentekapsule, met 'n bruin vulsel.

REGISTRASIONOMMER

Om deur SAHPRA toegeken te word by registrasie.

TOEGANG TOT DIE OOREENSTEMMENDE PROFESIONELE INLIGTING
Skandeer QR-kode.

HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP

19 Desember 2024

NAAM EN ADRES VAN REGISTRASIEHOUER

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