

PROFESSIONAL INFORMATION

SCHEDULING STATUS: S0

Category D: Complementary medicine.

Discipline: Discipline Specific

33.7 Combination Product



PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL

FORM - COLON ECOLOGY, 70 & 150 Capsules

COMPOSITION

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
Digezyme®	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)

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

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.

CONTRA INDICATIONS:

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

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)

DOSE AND 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.

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

You should 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 professional 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.
- 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. 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.

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 **COLON ECOLOGY** if you notice visible signs of deterioration.

IDENTIFICATION - Clear, vegetable capsule.

PRESENTATION

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.

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: 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.

Ingredients

Lactobacillus Sporogenes

Psyllium Seed Husk Powder

Slippery Elm (Ulmus rubra)

Bark

Barley Grass (Hordeum

vulgare) powder

Oat Bran (Avena sativa)

powder

Carrot (Daucus carota)

powder

FOS (Fructooligosaccharides)

Vitamin C (as Calcium

ascorbate)

Flaxseed (Linum

usitatissimum) powder

Aloe Vera (Aloe Vera) [Leaf

200:1 extract]

Prune (Prunus domestica)

powder

Digezyme®

Vitamin H (as biotin)

Uses for ingredient

It is used to improve the immune system and to treat diarrhoea and constipation.

Psyllium can help relieve both constipation and diarrhoea, and is used to treat irritable bowel syndrome, haemorrhoids, and other intestinal problems.

The inner bark contains chemicals that can increase mucous secretion, which might be helpful for stomach and intestinal problems. It also seems to slow stomach emptying which could keep blood sugar stable and help to control appetite. Oat bran might work by keeping the gut from absorbing substances that can lead to heart disease, high cholesterol, and diabetes.

Carrots can help support immune function, wound healing, and digestive health. This helps the good bacteria to grow, which is why they are used as prebiotics.

Vitamin C plays an important role in the immune system. Flaxseed is commonly used to improve digestive health or relieve constipation.

Aloe vera juice is known for its potential to support digestive health. Prunes contain a high amount of fibre, which helps prevent constipation by adding bulk to your stool.

DigeZyme® can digest these plant components and cellulosic material more efficiently since it contains cellulase and protease respectively. Biotin is also important for the body to metabolize fats, carbohydrates, and proteins.

PROFESIONELE INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

Kategorie D: Komplementêre medisyne.

Dissipline: Dissiplinespesifiek

33.7 Kombinasie produk

HANDELSNAAM EN DOSEERVORM,

COLON ECOLOGY, 70 & 150 Kapsules

SAMESTELING

Elke een (1) kapsules COLON ECOLOGY bevat die volgende aktiewe

stowwe:

Lactobacillus Sporogenes	198 Miljoen CFU
Psyllium Saad Skil Poeler	400 mg
Gladde Elm (Ulmus rubra) Bas	125 mg
Garsgras (Hordeum vulgare) poeler	100 mg
Hawersemels (Avena sativa) poeler	50 mg
Wortel (Daucus carota) poeler	50 mg
FOS (Fruktooligosakkariëde)	25 mg
Vitamiën C (as kalsiumskorbaat)	25 mg
Vlasaad (Linum usitatissimum) poeler	25 mg
Aloe Vera (Aloe Vera) [Blaar 200:1 uittreksel]	12,5 mg
Snoei (Prunus domestica) poeler	12,5 mg
Digezyme*	5 mg
Vitamiën H (as biotien)	200 µg

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

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

FARMAKOLOGIESE KLASIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

COLON ECOLOGY help om wind en opgeblasenheid te verlig en bevorder diergemedeerdheid. **COLON ECOLOGY** is 'n eie mengsel van hoë kwaliteit oplosbare en onoplosbare vesel, krukonsentraate, ensieme en voordelige probiotika.

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

Volwasse: Neem daaglik twee (2) kapsules op 'n leë maag met 'n ekstra glas water 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, hartsiektes, diabetes, kop- en nekkanke, swak en bros bene (osteoporose), prostaatkanke, 'n oorgeërfde oogtoestand wat swak nagsig en verlies aan visusie (retinitis pigmentosa) veroorsaak, beroerte, lewersiekte, post-chirurgiese stentpasing, Gewigsverlieschirurgie, prosedures om vernoude are (angioplastie) te verbreed, beslagleggingsversteuring. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidspraktisyn voordat jy neem: medisyne vir kanker (Chemoterapie), bloedstolling (Antikoagulant / Antiplaatjie-middels), Warfarin (Coumadin), Antibiotika vir kanker (Antitumour Antibiotika), Antibiotika (Tetraskilien antibiotika), Amiodarone (Cordarone), 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 ongevallende 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 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, wonderigheid.

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

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

IDENTIFIKASIE

Duidelike, groentekapsule.

AANBIEDING

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

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

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 BESIGHEIDSADRES 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.

Bestanddele

Lactobacillus Sporogenes	Gebruik vir bestanddeel Dit word gebruik om die immuunstelsel te verbeter en om diarree en hardlywigheid te behandel.
Psyllium Saad Skil Poeler	Psyllium kan help om hardlywigheid en diarree te verlig, en word gebruik om pikkelsbare dermindroom, aambeie en ander dermprobleme te behandel.
Gladde Elm (Ulmus rubra) Bas	Die binnebas bevat chemikalieë wat slymafskieding kan verhoeg, wat nuttig kan wees vir maag- en dermprobleme.
Garsgras (Hordeum vulgare) poeler	Dit lyk ook asof dit maagdigting verhoog wat bloedsuiker stabiel kan hou en help om eetlus te beheer.
Hawersemels (Avena sativa) poeler	Hawersemels kan werk deur te verhoed dat die ingewande stowwe absorbeer wat tot hartsiektes, hoë cholesterol en diabetes kan lei.
Wortel (Daucus carota) poeler	Wortels kan help om immuunfunksie, wondgeneesing en spysverteringsstelsel te ondersteun.
FOS (Fruktooligosakkariëde)	Dit help die goeie bakterieë om te groei, en daarom word hulle as prebiotika gebruik.
Vitamiën C (as kalsiumskorbaat)	Vitamiën C speel 'n belangrike rol in die immuunstelsel.
Vlasaad (Linum usitatissimum) poeler	Vlasaad word algemeen gebruik om spysverteringsstelsel te verbeter of hardlywigheid te verlig.
Aloe Vera (Aloe Vera) [Blaar 200:1 uittreksel]	Aloe vera-sap is bekend vir sy potensiële om spysverteringsstelsel te ondersteun.
Snoei (Prunus domestica) poeler	Pluimede bevat 'n groot hoeveelheid vesel, wat help om hardlywigheid te voorkom deur grootmaat by jou stoelgang te voeg.
Digezyme*	Digezyme* kan hierdie plantkomponente en sellulosemateriaal meer doeltreffend verteer, aansienlik dit onderskeidelik sellulose en protease bevat.
Vitamiën H (as biotien)	Biotien is ook belangrik vir die liggaam om vette, koolhidrate en proteïene te metaboliseer.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn 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 gesondheidsorgpraktisyn gaan voordat jy hierdie aanvulling neem.

Chirurgie: **COLON ECOLOGY** kan die risiko van bloeding tydens en na die operasie verhoeg. Hou op om **COLON ECOLOGY** ten minste 2 weke voor 'n geskeduleerde operasie te gebruik. **Laboratoriumtoetse:** Biotiëaanvullings kan inmeng met die resultate van baie verskillende bloedlaboratoriumtoetse. Biotien kan vals hoë of vals lae toetsresultate veroorsaak. Dit kan lei tot gemiste of verkeerde diagnoses. Vertel jou dokter as jy biotiëaanvullings neem, veral as jy laboratoriumtoetse laat doen.

Antibiotika: Neem jou antibiotika 2 ure voor of na die neem van **COLON**

ECOLOGY.