FIBRELLE CAPSULES

SCHEDULING STATUS:

Not applicable

PROPRIETARY NAME AND DOSAGE FORM:

FIBRELLE CAPSULES

COMPOSITION:

Each **FIBRELLE** CAPSULE contains:

Psyllium Husks	336,00 mg
Lactobacillus rhamnosus (UALR-06)	1 x 10^9 cfu
Bifidobacterium longum (UABL-14)	1 x 10^9 cfu
Fructo-oligosaccharides	80,00 mg

Contains no added sugar, salt, yeast, wheat, soy, nuts, dairy products, and is free from preservatives and flavourants.

PHARMACOLOGICAL CLASSIFICATION:

A. 32.2 Other substances or agents, other

PHARMACOLOGICAL ACTION:

Psyllium Husk is a seed from the common fleawort, *Plantago Psyllium* plant. Psyllium contains a high level of soluble dietary fibre. Fibre is used to soften stools and ease bowel movements involving the anus and rectum, when haemorrhoids or anal fissures are present to lessen the strain of bowel movements, for example after operations. Psyllium husks are coated with a substance called mucilage that swells or "bulks up" when exposed to water. This extra volume stimulates the movement of material through the bowel. In addition, the moist, gummy mucilage lubricates the lining of the intestine.
Lactobacillus rhamnosus and *Bifidobacterium longum* are probiotics.
Probiotics compete with pathogenic bacteria for enteric sites (within the intestine) thereby inhibiting the pathogenic bacteria from establishing themselves.

Furthermore, probiotics compete with pathogenic bacteria for nutrients thereby inhibiting the pathogenic bacteria from multiplying (proliferating) and becoming the dominant bacteria.

Prebiotics, fructo-oligosaccharides, are a source of food and thereby help support the growth of probiotics in the gut. Prebiotics are not digested by the body.

INDICATIONS:

A hectic daily schedule, stress and unhealthy eating habits, result in a feeling of general discomfort most associated with altered bowel movements.

The combination of substances in **FIBRELLE** CAPSULES assists in restoring the balance and helps the human body maintain natural bowel health.

CONTRA-INDICATIONS:

Do not use **FIBRELLE** CAPSULES under the following circumstances:

- An inherited disorder of protein metabolism (phenylketonuria)
- Blockage of the gut (intestinal obstruction)
- Compressed and hardened faeces causing a blockage of the bowel (faecal impaction)
- Difficulty in swallowing.

This product should not be used if you are allergic to one or any of its ingredients.
Please inform your doctor or pharmacist if you have previously experienced such an allergy.

If you feel you have experienced an allergic reaction, stop using this product and inform your doctor or pharmacist immediately.

WARNINGS:

You should ensure that you drink plenty of fluids while taking this product.
This product should not be taken shortly before going to bed.
Preparations that swell in contact with liquid should always be carefully swallowed with lots of water.

INTERACTIONS:

The psyllium husk component might result in a decrease in the absorption of antidiabetic medicines.

PREGNANCY AND LACTATION:

Do not exceed the recommended dosage.

DOSAGE AND DIRECTIONS FOR USE:

FIBRELLE CAPSULES should be taken with plenty of fluid.

Adults and children over 12 years: Take two **FIBRELLE** CAPSULES in the morning and the evening swallowed whole with lots of water or fruit juice, unless otherwise specified by your healthcare professional. Do not exceed the recommended daily dose.

The full effect may take some days to be seen.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

This product can affect individual people in different ways. The following are some of the side-effects that are known to be associated with some of the ingredients in this product. Because a side-effect is stated here, it does not mean that all people using this product will experience that or any side-effects:

- Excess gas in the stomach and intestines (flatulence)
- Swelling of abdomen (abdominal distension)
- Bloating.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

In the event of overdosage the patient may notice abdominal discomfort and flatulence. Attention should be provided in maintaining an adequate fluid intake, particularly if the capsules have been taken without water contrary to administration instructions. Treatment of overdosage should be symptomatic and supportive. In the case of accidental overdose of the product, contact the nearest hospital or poison control centre.

IDENTIFICATION:

Green opaque body and cap capsules containing a brown powder.

PRESENTATION:

A white HDPE meditainer having a green screw on cap containing 120 capsules.

STORAGE INSTRUCTIONS:

Store in a cool (below 25°C), dry place. Protect from moisture.

KEEP OUT OF REACH OF CHILDREN

NAME AND BUSINESS ADDRESS:

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FIBRELLE KAPSULES

SKEDULERINGSTATUS:

Nie van toepassing nie.

EIENDOMSNAAM EN DOSEERVORM:

FIBRELLE KAPSULES

SAMESTELLING:

Elke **FIBRELLE** KAPSULE bevat:

Psyllium Peul	336,00 mg
Lactobacillus rhamnosus (UALR-06)	1 x 10^9 kve
Bifidobacterium longum (UABL-14)	1 x 10^9 kve
Frukto-oliegosakkariede	80,00 mg

Bevat geen bygevoegde suiker, sout, gis, koring, soja, neute, of suiwelprodukte nie, en is vry van preserveermiddels en geurmiddels.

FARMAKOLOGIESE KLASSIFISERING:

A. 32.2 Ander stowwe of middels, ander.

FARMAKOLOGIESE WERKING:

Psyllium Peul is 'n saad van die gewone vlooikruid, *Plantago Psyllium* plant. Psyllium bevat 'n groot hoeveelheid oplosbare dieetvesel. Vesel word gebruik om stoelgang sag te maak en dermbewegings wat die anus en rektum betrek, te vergemaklik wanneer aambeie of anale fissure teenwoordig is om die inspanning van dermbewegings te verminder, byvoorbeeld na operasies. Psyllium peule is oortrek met 'n slymerige stof wat opswel of "volume vergroting" veroorsaak wanneer dit aan water blootgestel word. Hierdie ekstra volume stimuleer die beweging van materiaal deur die derm. Daarbenewens lubrikeer die vogtige, slymerige stof die voering van die dermkanaal.

Lactobacillus rhamnosus en *Bifidobacterium longum* is probiotika.
Probiotika kompeteer met patogene bakterieë vir enteriese setels (binne die dermkanaal), en inhibeer dus die vestiging van die patogene bakterieë.
Daarbenewens kompeteer probiotika met patogene bakterieë vir voedingstowwe waardeur vermenigvuldiging (proliferasie) van die patogene bakterieë en hulle vestiging as die dominante bakterie geïnhibeerd word.

Prebiotika, frukto-oliegosakkariede, is voedselbronne en help om die groei van probiotika in die spysverteringskanaal te ondersteun. Prebiotika word nie deur die liggaam verteer nie.

INDIKASIES:
'n Bedrywige daaglikse skedule, stres en ongesonde eetgewoontes, veroorsaak 'n gevoel van algemene ongemak wat meestal met veranderde dermbewegings geassosieer word.

Die kombinasie van stowwe in **FIBRELLE** KAPSULES help om die balans te herstel en help ook die menslike liggaam om natuurlike dermgesondheid te onderhou.

KONTRA-INDIKASIES:
Moenie **FIBRELLE** KAPSULES onder die volgende omstandighede gebruik nie:

- 'n Aangebore versteuring van proteïenmetabolisme (fenielketonurie)
- Verstopping van die derm (intestinale obstruksie)
- Saamgepersde en harde faeces wat blokkering van die dermkanaal veroorsaak (fekale impaksie)
- As daar probleme met sluk bestaan.

Hierdie produk behoort nie gebruik te word indien jy vir een of enigeen van die bestanddele allergies is nie.
Lig jou dokter of apteker asseblief in as jy in die verlede so 'n allergie ondervind het.

Indien jy voel dat jy 'n allergiese reaksie ondervind het, moet jy hierdie produk staak en jou dokter of apteker onmiddellik daarvan vertel.

WAARSKUWINGS:

Jy moet verseker dat jy baie vloeistof drink terwyl jy hierdie produk neem.
Hierdie produk behoort nie kort voor slapenstyd geneem te word nie.
Preparate wat opswel as hulle in aanraking kom met vloeistof behoort altyd versigtig met baie water gesluk te word.

INTERAKSIES:

Die psyllium peul komponent mag 'n verlaging in die absorpsie van antidiabetiese medisyne veroorsaak.

SWANGERSKAP EN LAKTASIE:

Moenie die aanbevole dosering oorskry nie.

DOSERING EN GEBRUIKSAANWYSINGS:

FIBRELLE KAPSULES moet met baie vloeistof geneem word.
Volwassenes en kinders ouer as 12 jaar**:** Neem twee **FIBRELLE** KAPSULES in die oggend en in die aand wat heel ingesluk word saam met baie water of vrugtesap, tensy anders voorgeskryf deur 'n lid van die gesondheidsorgspan. Moenie die aanbevole daaglikse dosis oorskry nie.
Dit mag 'n paar dae neem voordat die volle effek waargeneem word.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:

Hierdie produk mag individuele persone op verskillende maniere beïnvloed. Die volgende is sommige van die newe-effekte waar dit bekend is dat hulle met sommige van die bestanddele in hierdie produk geassosieer word. Omdat 'n newe-effek hier genoem word, beteken dit egter nie dat alle persone wat hierdie produk gebruik, daardie of enige ander newe-effek sal ondervind nie:

- Oormatige gas in die maag en dermkanaal (winderigheid)
- Swelling van die buik (abdominale uitsetting)
- Opblaassiekte.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Indien oordosering sou plaasvind, mag die pasiënt bewus word van abdominale ongemak en winderigheid. Aandag moet gegee word om 'n toereikende vloeistofinname te verseker, veral as die kapsules, in teenstelling met die toedieningsinstruksies, sonder water geneem is.

Behandeling van oordosering behoort simptomaties en ondersteunend te wees. In 'n geval van oordosering van die produk wat per abuis voorkom, moet die naaste hospitaal of gifbeheersentrum gekontak word.

IDENTIFIKASIE:

Kapsules met 'n groen ondeurskynende romp en dop, wat 'n bruin poeier bevat.

AANBIEDING:

'n Wit HDPE medihouer wat 'n groen skroefdop het en 120 kapsules bevat.

BERGINGSAANWYSINGS:

Bewaar in 'n koel (onder 25^{o}C), droë plek. Beskerm teen vog.

HOU BUITE BEREIK VAN KINDERS.

NAAM EN BESIGHEIDSADRES:

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