

SCHEDULING STATUS [S0]

Not scheduled

PROPRIETARY NAME AND DOSAGE FORM:

GutFora™ Probiotic Capsules

Each capsule contains:

Ingredients	Per capsule
Total probiotic count	1 Billion CFU*
Bifidobacterium lactis (HN019)	500 Million CFU*
Lactobacillus casei (LC-11)	500 Million CFU*
Prebiotic (Inulin)	100 mg

* CFU – Colony Forming Units.

Other ingredients:

Gelatin (Capsule), Magnesium Stearate, Maize Starch. Contains no sugar.

PHARMACOLOGICAL CLASSIFICATION

34.9 Category D (Health Supplement) [S0] - Probiotic

INDICATIONS

When ingested on a regular basis, probiotics should improve or normalise the microbial balance in the human intestines and thereby improve the functioning of the digestive tract.

Prebiotics such as (Inulin) beneficially affects the intestinal flora by selectively stimulating the growth of the good/ beneficial gut flora/micro-organisms which positively affects intestinal health. An average of 6 g prebiotics is needed daily for general digestive health.

CONTRAINDICATIONS

Hypersensitivity to any of the ingredients.

If you are pregnant or breastfeeding your baby, please consult your health care provider for advice before taking this medicine.

WARNINGS AND SPECIAL PRECAUTIONS

Do not exceed the recommended dose. Always follow all directions on your medicine label and packaging. Not recommended for children under the age of 3 years.

KEEP OUT OF REACH OF CHILDREN.

INTERACTIONS

If you are taking other medicines regularly, including complementary or traditional medicines, or start taking any additional medicines while taking this medicine, consult your healthcare provider for advice. Taking antibiotics along with this medicine can reduce the effectiveness of this medicine. To avoid this interaction take this medicine at least two hours after antibiotics.

DOSAGE AND DIRECTIONS FOR USE

Adults and children ≥ 3 years: Take 1 capsule daily. Dosage can be increased to 2 capsules per day if needed or as directed by your healthcare professional. Take this medicine at least two hours after antibiotics.

Do not share medicines prescribed for you with any other person. In the event of over-dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

SIDE EFFECTS

Side effects can include intestinal gas and bloating. Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any side effects while taking this medicine, discontinue use immediately and consult your doctor, pharmacist or other healthcare provider for advice.

STORAGE INSTRUCTIONS

Store in a cool, dry place below 25 °C. Do not store it in a fridge. Store in original packaging until required for use. Keep away from direct sunlight.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION

A printed unit carton containing 10 or 30 GutFora™ probiotic capsules (packaged in a blister strip with 10 capsules each).

IDENTIFICATION

White capsules.

REGISTRATION NUMBER

To be allocated.

APPLICANT

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™ = Trademark.

DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

August 2022.

Complementary Medicine: Health Supplement
Classification D (HS)

This medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. This medicine is not intended to diagnose, treat, cure or prevent any disease.

HANDELSNAAM EN DOSERINGSVORM:
GutFora™ Probiotic Capsules

Elke kapsule bevat:

Bestanddele	Per kapsule
Totale probiotiese telling	1 Miljard KVE*
Bifidobacterium lactis (HN019)	500 Miljoen KVE*
Lactobacillus casei (LC-11)	500 Miljoen KVE*
Prebiotikum (Inulien)	100 mg

* KVE – Kolonie Vormende Eenhede.

Ander bestanddele:
Gelatin (Kapsule), Magnesiumstearaat, Mieliestysel. Bevat geen suiker.

FARMAKOLOGIESE KLASSIFIKASIE
34.9 Kategorie D (Gesondheidsaanvuller) [S0] - Probiotika

INDIKASIES
Met gereelde inname behoort probiotika die mikrobiologiese balans in die menslike ingewande te verbeter of normaliseer en sodoende, die funksionering van die spysverteringskanaal verbeter.

Prebiotika soos (Inulien) beïnvloed die dermflora voordelig deur selektief die groei van die goeie/voordelige dermflora/mikro-organismes te stimuleer wat dermgesondheid positief beïnvloed. 'n Gemiddelde van 6 g prebiotika word daaglik benodig vir algemene spysverteringstelsel gesondheid.

KONTRA-INDIKASIES
Hipersensitiwiteit vir enige van die bestanddele.
Indien swanger of borsvoed, raadpleeg jou gesondheidsorgverskaffer voordat hierdie medisyne gebruik word.

WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS
Moenie die aanbevole dosis oorskry nie. Volg altyd alle aanwysings op jou medisyne etiket en verpakking.
Nie aanbeveel vir kinders onder die ouderdom van 3 jaar nie.

HOU BUITE BEREIK VAN KINDERS.

INTERAKSIES
As jy ander medisyne gereeld gebruik, insluitend aanvullende (komplimentêre) of tradisionele medisyne, of as jy enige addisionele medisyne begin neem terwyl jy hierdie medisyne gebruik, raadpleeg jou geneesheer vir raad. Antibiotika kan die effektiwiteit van hierdie medisyne beïnvloed indien dit saam gebruik word. Neem die medisyne ten minste twee ure na antibiotika om die interaksie te vermy.

DOSERING EN GEBRUIKSAANWYSINGS:
Volwassenes en kinders ≥ 3 jaar: Neem 1 kapsule daaglik. Dosis kan verhoog word tot 2 kapsules indien nodig of soos aanbeveel deur 'n professionele gesondheidsorgkundige. Neem die medisyne ten minste twee ure na antibiotika.

Moenie medisyne met enige ander persoon deel nie. In die geval van 'n oordosis, raadpleeg dadelik u gesondheidsorgverskaffer. Indien nie beskikbaar, kontak die naaste hospitaal of mediese sentrum vir advies.

NEWE-EFFEKTE
Newe-effekte kan intestinale gas en opgeblaasheid insluit. Nie alle neue-effekte is in hierdie voubiljet gelys nie. Indien u algemene gesondheidstoestand versleg of as u enige neue-effekte ervaar, hou onmiddellik op om die medisyne te gebruik en raadpleeg jou dokter, apteker of ander gesondheidsorgverskaffer vir advies.

BERGINGSINSTRUKSIES
Berg in 'n koel, droë plek onder 25 °C. Moet dit nie in 'n yskas bêre nie. Bêre in oorspronklike verpakking totdat dit benodig word vir gebruik. Hou weg van direkte sonlig.

STOOR ALLE MEDISYNE BUITE BEREIK VAN KINDERS.

AANBIEDING
'n Gedrukte eenheidskarton wat 10 of 30 GutFora™ probiotiese kapsules bevat (verpak in 'n blaasverpakkingstrook met 10 kapsules elk).

IDENTIFIKASIE
Wit kapsules.

REGISTRASIE NOMMER
Om toegeken te word.

AANSOEKER
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™ = Handelsmerk.

DATUM VAN PUBLIKASIE VAN HIERDIE PASIËNT INLICHTING PAMFLET
Augustus 2022.

Aanvullende Medisyne: Gesondheidsaanvuller
Klassifikasie: D (HS)
Hierdie medisyne is nie deur SAHPRA geëvalueer ten opsigte van die kwaliteit, veiligheid of beoogde gebruik daarvan nie. Hierdie medisyne is nie bedoel vir die diagnosering, behandeling, genesing of voorkoming van enige siekte nie.