

SCHEDULING STATUS: Nutritional supplement (Act 54/1972)

PACKAGE INSERT

PROPRIETARY NAME (AND DOSAGE FORM): BIFIDOFLORA® capsules

COMPOSITION: Each capsule contains 22,2 mg of a probiotic mixture consisting of *Bifidobacterium bifidum* and *Bifidobacterium longum* (in a lyophilized form), which yields in total not less than 1 billion (10⁹) viable cells.

PHARMACOLOGICAL ACTION: BIFIDOFLORA® capsules contain a mixture of lyophilised lactic acid bacteria namely, *Bifidobacterium bifidum* and *Bifidobacterium longum* which are natural inhabitants of the human large intestine.

BIFIDOFLORA® is administered to restore the normal intestinal bifidobacteria destroyed by broad-spectrum antibiotics, therefore limiting the overgrowth of pathogenic organisms. Administration of high doses of these bacteria helps to prevent diarrhoea associated with broad-spectrum antibiotic treatment. The resulting increase in the indigenous intestinal bacteria enhances the inhibition of the growth of pathogens.

INDICATIONS: BIFIDOFLORA® "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/gut" (S0)

CONTRA-INDICATIONS: None known

DOSAGE AND DIRECTIONS FOR USE: FOR ADULTS:

Treatment dose: 3 capsules to be taken three times per day with water (preferably on an empty stomach, 30 minutes before meals), for 1 to 2 weeks. In conjunction with antibiotic therapy continue with the treatment for at least one week after the completion of the therapy.

Maintenance dose: 1 capsule to be taken three times per day with water (preferably on an empty stomach, 30 minutes before meals).

FOR CHILDREN: 1 to 6 years old: 1 capsule per day; 7 to 14 years old: 2 capsules per day; For children above 14 years: an adult dose is recommended.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS: Large doses may cause loose stools in some individuals.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT: Loose stools whereupon the administration of BIFIDOFLORA® should be discontinued temporarily.

IDENTIFICATION: White gelatine capsules containing white to cream coloured, granular material with a slight lactic acid smell.

PRESENTATION: 90 capsules in Securitainers.

STORAGE INSTRUCTIONS: Store below 8°C (in refrigerator or freezer)

KEEP OUT OF REACH OF CHILDREN.

DATE OF PUBLICATION OF THIS PACKAGE INSERT: March 2017

NAME AND BUSINESS ADDRESS OF MANUFACTURER:

Bioflora® cc

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SKEDULERINGSTATUS: Voedingsaanvulling (Wet 54/1972)

VOUBILJET

EIENDOMSNAAM (EN DOSEERVORM): BIFIDOFLORA® kapsules

SAMESTELLING: Elke kapsule bevat 22,2 mg van 'n probiotiese mengsel wat bestaan uit *Bifidobacterium bifidum* en *Bifidobacterium longum* (in 'n geliofiliseerde vorm), wat in totaal nie minder as 1 biljoen (10⁹) lewensvatbare selle, verskaf.

FARMAKOLOGIESE WERKING: BIFIDOFLORA® kapsules bevat 'n mengsel van geliofiliseerde melksuurbakterieë naamlik, *Bifidobacterium bifidum* en *Bifidobacterium longum* wat natuurlik in die menslike dikderm voorkom.

BIFIDOFLORA® word toegedien om die normale intestinale bifidobakterieë wat deur breë-spektrum antibiotika vernietig word, te herstel waardeur die oormatige groei van patogene organismes beperk word. Toediening van hoë dosisse van hierdie bakterieë help om diarree te verhoed wat met behandeling met breë-spektrum antibiotika geassosieer word. Die gevolglike toename in die inheemse intestinale bakterieë versterk die inhibisie van die groei van patogene.

INDIKASIES: BIFIDOFLORA® “Wanneer dit gereeld ingeneem word, behoort dit die mikrobiële balans in die menslike ingewande te verbeter en daardeur die funksionering van die spysverteringstelsel/ingewande te verbeter” (S0)

KONTRA-INDIKASIES: Geen bekend nie.

DOSES EN GEBRUIKSAANWYSINGS: VIR VOLWASSENES:

Behandelingsdosis: 3 kapsules moet drie keer per dag met water (liefs op 'n leë maag, 30 minute voor etes), vir 1 tot 2 weke geneem word. In samewerking met antibiotiese terapie moet met die behandeling vir ten minste een week na voltooiing van die terapie, voortgegaan word.

Onderhoudsdosis: 1 kapsule moet drie keer per dag met water (liefs op 'n leë maag, 30 minute voor etes), geneem word.

VIR KINDERS: 1- tot 6-jarige ouderdom: 1 kapsule per dag; 7- tot 14-jarige ouderdom: 2 kapsules per dag; Vir kinders ouer as 14 jaar: word 'n volwasse dosis aanbeveel.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS: Groot dosisse mag los stoelgang by sommige individue veroorsaak.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING

DAARVAN: Los stoelgang waarna die toediening van BIFIDOFLORA® tydelik gestaak moet word.

IDENTIFIKASIE: Wit gelatienekapsules wat wit tot roomkleurige, granulêre materiaal bevat met 'n effense melksuurgeur.

AANBIEDING: 90 kapsules in Sekurihouers.

BERGINGSINSTRUKSIES: Bewaar onder 8°C (in 'n yskas of vrieskas).

HOU BUIE BEREIK VAN KINDERS.

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET: Maart 2017

NAAM EN BESIGHEIDSADRES VAN DIE VERVAARDIGER:

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