

PACKAGE INSERT

SCHEDULING STATUS: Schedule 0 of Act 101 of 1965

PROPRIETARY NAME (AND DOSAGE FORM):

INFANTIFLORA® capsules

COMPOSITION:

Each capsule contains 12,9 mg consisting of *Bifidobacterium infantis* (in a lyophilised form), which yields not less than 1 billion (10⁹) viable cells.

PHARMACOLOGICAL ACTION:

INFANTIFLORA® capsules contain cells of *Bifidobacterium infantis*, a species which is a natural inhabitant of the infant's intestinal tract.

INFANTIFLORA® is administered to restore the normal intestinal bifidobacteria destroyed by antibiotics, therefore limiting the overgrowth of pathogenic organisms in the intestines. Administration of high doses of these bacteria helps to prevent diarrhoea associated with antibiotic treatment.

INDICATIONS:

INFANTIFLORA® "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 infants 0 - 12 months:

In conjunction with antibiotic therapy: The contents of 1 to 3 capsules to be taken per day suspended in a liquid or in a baby formulae, after cooling the liquid to body temperature. Continue with the treatment for at least one week after the completion of antibiotic therapy. In cases of acute diarrhoea the dosage can be increased to 2 capsules three times per day.

Restoration dose: 1 capsule to be taken two times per day suspended in a liquid, for 1 to 2 weeks.

Maintenance dose: 1 capsule per day suspended in a liquid.

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 **INFANTIFLORA®** should be discontinued temporarily.

IDENTIFICATION:

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

PRESENTATION:

30 Screw Top Containers.

STORAGE INSTRUCTIONS:

Store below 8°C (in refrigerator or freezer)

KEEP OUT OF REACH OF CHILDREN.

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

February 2015

NAME AND BUSINESS ADDRESS OF MANUFACTURER:

Bioflora cc (Reg No: 1995/020581/23)

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VOUBILJET

SKEDULERINGSSTATUS: Voedingsaanvulling (Wet 54/1972)

EIENDOMSNAAM (EN DOSEERVORM):
INFANTIFLORA® kapsules

SAMESTELLING:

Elke kapsule bevat 12,9 mg van *Bifidobacterium infantis* (in 'n geliofiliseerde vorm), wat nie minder as 1 biljoen (10⁹) lewensvatbare selle, verskaf.

FARMAKOLOGIESE WERKING:

INFANTIFLORA® kapsules bevat selle van *Bifidobacterium infantis*, 'n spesie wat natuurlik in die suigeling se dermkanaal voorkom.

INFANTIFLORA® word toegedien om die normale intestinale bifidobakterieë wat deur antibiotika vernietig word, te herstel waardeur die oormatige groei van patogene organismes in die dermkanaal beperk word. Toediening van hoë dosisse van hierdie bakterieë help om diarree te verhoed wat met behandeling met antibiotika geassosieer word.

INDIKASIES:

INFANTIFLORA® "Wanneer ingeneem op 'n gereelde basis, moet probiotika die mikrobiologiese balans verbeter of normaliseer in die menslike ingewande en sodoende die funksionering van die spysverteringstelsel/ingewande verbeter":(S0)

KONTRA-INDIKASIES:

Geen bekend nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Vir suigeling van 0-12 maande:

In samewerking met antibiotiese terapie: Die inhoud van 1 tot 3 kapsules wat in 'n vloeistof of in 'n babaformule gesuspendeer is, moet daaglik geneem word nadat die vloeistof tot by liggaamstemperatuur afgekoel is. Daar moet met die behandeling vir ten minste een week na voltooiing van die antibiotiese terapie, voortgegaan word. In gevalle van akute diarree kan die dosis tot 2 kapsules drie keer per dag verhoog word.

Herstdosis: 1 kapsule wat in 'n vloeistof gesuspendeer is, moet twee keer per dag vir 1 tot 2 weke geneem word.

Onderhoudsdosis: 1 kapsule gesuspendeer in 'n vloeistof.

NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:

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 **INFANTIFLORA®** tydelik gestaak moet word.

IDENTIFIKASIE:

Wit gelatienkapsules wat wit tot roomkleurige, granulêre materiaal bevat met 'n effense melksuurgeur.

AANBIEDING:

30 in Skroef Prop houers.

BERGINGSINSTRUKSIES:

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

HOU BUIE BEREIK VAN KINDERS.

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:

Februarie 2015

NAAM EN BESIGHEIDSADRES VAN DIE VERVAARDIGER:

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