

## PACKAGE INSERT

**SCHEDULING STATUS:** Nutritional supplement (Act 54/1972)

**PROPRIETARY NAME (AND DOSAGE FORM):**

**KIDDIEFORTE<sup>®</sup>** chewable tablets

**COMPOSITION:**

Each tablet contains 12.9 mg of a probiotic mixture consisting of *Lactobacillus acidophilus*, *Bifidobacterium bifidum* and *Bifidobacterium longum* (in a lyophilised form), which yields in total not less than 1 billion ( $10^9$ ) viable cells, and 300 mg of a prebiotic, fructo-oligosaccharide, which selectively supports the growth of probiotic strains.

**PHARMACOLOGICAL ACTION:**

**KIDDIEFORTE<sup>®</sup>** tablets contain a mixture of lyophilised lactic acid bacteria namely, *Lactobacillus acidophilus*, *Bifidobacterium bifidum* and *Bifidobacterium longum* which are natural inhabitants of children's intestines.

**KIDDIEFORTE<sup>®</sup>** is administered to restore the normal intestinal lactobacilli and 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.

**INDICATIONS:**

**KIDDIEFORTE<sup>®</sup>** "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

**DOSE AND DIRECTIONS FOR USE:**

**Treatment dose:** 2 tablets to be chewed 3 times per day (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 tablet per day to be chewed (preferably on an empty stomach, 30 minutes before meals).

**SIDE-EFFECTS AND SPECIAL PRECAUTIONS:**

Large doses may cause loose stools in some children.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

Loose stools whereupon the administration of **KIDDIEFORTE<sup>®</sup>** should be discontinued temporarily.

**IDENTIFICATION:**

White oval shaped chewable tablets with a slight lactic acid smell.

**PRESENTATION:**

30, tablets in 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:**

January 2018

**NAME AND BUSINESS ADDRESS OF MANUFACTURER**

Bioflora cc (RegNo: 1995/020581/23)

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## VOUBILJET

**SKEDULERINGSSTATUS:** voeding aan te vul (Wet 54/1972)

**EIENDOMSNAAM (EN DOSEERVORM):**

**KIDDIEFORTE®** koubare tablette

**SAMESTELLING:**

Elke tablet bevat 12,9 mg van 'n probiotiese mengsel bestaande

uit *Lactobacillus acidophilus*, *Bifidobacterium bifidum* en *Bifidobacterium longum* (in 'n gevriesdroogde vorm), wat opbrengste in totaal nie minder nie as 1 miljard ( $10^8$ ) lewensvatbare selle, en 300 mg van 'n prebiotiese, frukto-oligosakkaried, wat selektief die groei van probiotika stamme ondersteun.

**FARMAKOLOGIESE WERKING:**

KIDDIEFORTE® tablette bevat 'n mengsel

van gevriesdroogde melksuurbakterieë naamlik *Lactobacillus acidophilus*, *Bifidobacterium bifidum* en *Bifidobacterium longum* wat natuurlike inwoners van kinders se ingewande is.

KIDDIEFORTE® word geadminestreer om die normale intestinale *Lactobacillus* en *Bifidobacterium* wat vernietig word deur 'n breë spektrum antibiotika te herstel, en beperk sodoende die oorgroei van patogene organismes. Administrasie van hoë dosisse van hierdie bakterieë help om diarree geassosieer met 'n breë spektrum antibiotika te voorkom.

**INDIKASIES:**

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

**KONTRA-INDIKASIES:**

Geen bekend

**DOSIS EN GEBRUIKSAANWYSINGS:**

**Behandeling Dosis:** 2 tablette gekou word 3 keer per dag (verkieslik op 'n leë maag, 30 minute voor etes), vir 1 tot 2 weke. In samewerking met antibiotika terapie, voort te gaan met die behandeling vir ten minste een week na die voltooiing van die terapie.

**Instandhoudingsdosis:** 1 tablet per dag (verkieslik op 'n leë maag, 30 minute voor etes).

**NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:**

Groot dosisse kan los stoelgange veroorsaak in sommige kinders.

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING:**

Los stoelgange waarna die administrasie van KIDDIEFORTE® tydelik gestaak moet word.

**IDENTIFIKASIE:**

White ovaalvormige koubare tablette met 'n effense melksuur reuk.

**AANBIEDING:**

30, in n draai top houer.

**BERIGINGSAAANWYSINGS:**

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

**HOU BUIE BEREIK VAN KINDERS.**

**DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:**

Januarie 2018

**NAAM EN BESIGHEIDSADRES VAN VERVAARDIGER**

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**INFANTIFORTE® Spray** PACKAGE INSERT

**PROPRIETARY NAME (AND DOSAGE FORM):** INFANTIFORTE® Spray: 90 dosages per bottle.

**COMPOSITION:** Each squirt of the probiotic spray has a volume of approximately 250 µl (microliters) and contains 2 billion CFU (colony forming units) of *Bifidobacterium infantis*.

**METHOD OF ACTION:** INFANTIFORTE® Spray contains lyophilised cells of *Bifidobacterium infantis*, a species which is a natural inhabitant of the infant's intestinal tract. INFANTIFORTE® Spray is administered to help restore the normal intestinal bifidobacteria destroyed by antibiotics, to support a healthy digestive system and to balance normal bowel flora. Administration of high doses of these bacteria may help to manage the bowel flora imbalance associated with antibiotic treatment.

**INDICATIONS:** INFANTIFORTE® Spray: "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"

**CONTRA-INDICATIONS:** None known

**DOSAGE AND DIRECTIONS FOR USE: For infants 0 - 12 months:**

In conjunction with antibiotic therapy: one to three squirts per day to be administered to the infant's mouth. Continue with the treatment for at least one week after the completion of antibiotic therapy.

**Restoration dose:** 1 squirt to be administered two times per, for 1 to 2 weeks.

**Maintenance dose:** 1 squirt per day is recommended.

**SHAKE BOTTLE VERY WELL PRIOR TO APPLICATION. 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 INFANTIFORTE® Spray should be discontinued temporarily. **PRESENTATION:** Amber spray bottle with metered spray insert

**STORAGE INSTRUCTIONS:** Store below 25°C

**KEEP OUT OF REACH OF CHILDREN.  
ALWAYS READ THE LABEL AND USE AS DIRECTED.**

**IF SYMPTOMS PERSIST, SEE YOUR HEALTHCARE PROFESSIONAL.**

**DATE OF PUBLICATION OF THIS PACKAGE INSERT:** July 2012

**NAME AND BUSINESS ADDRESS OF THE MANUFACTURER:**

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**NAME AND BUSINESS ADDRESS OF APPLICANT:**

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**INFANTIFORTE® Sproei** VOUBILJET

**SKEDULERINGSSTATUS:** Voedingsaanvulling (Wet 54/1972)

**EIENDOMSNAAM (EN DOSEERVORM):**  
INFANTIFORTE® Sproei: 90 dosisse per bottel.

**SAMESTELLING:**

Elke probiotiese sproei van die sproei-bottel het 'n volume van ongeveer 250 µl (mikroliter) en bevat 2 biljoen KVE (kolonievormende eenhede) van *Bifidobacterium infantis*.

**FARMAKOLOGIESE WERKING:**

INFANTIFORTE® Sproei bevat gekultiveerde selle van *Bifidobacterium infantis*, 'n spesies wat natuurlik in die dermkanaal van die suigeling voorkom. INFANTIFORTE® Sproei word toegedien om die normale intestinale bifidobakteriële wat deur antibiotika vernietig word, te herstel en sodoende die oormatige groei van patogeen organismes in die dermkanaal te beperk. Toediening van hoër dosisse van hierdie bakteriële help om die diarree wat met antibiotika-behandeling geassosieer word, te verhoed.

**INDIKASIES:**

INFANTIFORTE® "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"

**KONTRA-INDIKASIES:**

Geen bekend nie.

**DOSIS EN GEBRUIKSAANWYSINGS: Vir suigeling van 0-12 maande:**

In samewerking met antibiotiese terapie: een tot drie sproeie per dag moet in die suigeling se mond toegedien word. Gaan voort met die behandeling vir ten minste een week na voltooiing van die antibiotiese terapie. In gevalle van akute diarree, kan die dosis verhoog word tot 2 sproeie drie keer per dag.

**Herstedosis:** 1 sproei wat twee keer per dag toegedien word vir 1 tot 2 weke.

**Onderhoudsdosis:** 1 sproei per dag word aanbeveel.

**SKUD BOTTEL BAIE DEEGLIK VOOR AANWENDING**

**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 INFANTIFORTE® Sproei tydelik gestaak moet word.

**AANBIEDING:**

Amberkleurige sproei-bottel met 'n afgemete sproei-toestel.

**BERGINGSINSTRUKSIES:**

Bewaar onder 25°C.

**HOU BUITE BEREIK VAN KINDERS.**

**DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:**

Julie 2012.

**NAAM EN BESIGHEIDSADRES VAN DIE VERVAARDIGER:**

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## **PACKAGE INSERT**

**SCHEDULING STATUS:** Nutritional supplement (Act 54/1972)

**PROPRIETARY NAME (AND DOSAGE FORM):**

**COMBIFORTE<sup>®</sup> capsules**

**COMPOSITION:**

Each capsule contains 12,9 mg of a probiotic mixture consisting of *Lactobacillus acidophilus*, *Bifidobacterium bifidum* and *Bifidobacterium longum* (in a lyophilized form), which yields in total not less than 1 billion (10<sup>9</sup>) viable cells, and 300 mg of fructo-oligosaccharide, a prebiotic.

**PHARMACOLOGICAL ACTION:**

**COMBIFORTE<sup>®</sup>** capsules contain a mixture of lyophilised lactic acid bacteria namely, *Lactobacillus acidophilus*, *Bifidobacterium bifidum* and *Bifidobacterium longum* which are natural inhabitants of the human intestine.

**COMBIFORTE<sup>®</sup>** is administered to restore the normal intestinal lactobacilli and 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. Fructo-oligosaccharide further improves human health by selectively supporting the growth of probiotic strains. The resulting increase in the indigenous intestinal bacteria enhances the inhibition of the growth of pathogens.

**INDICATIONS:**

**COMBIFORTE<sup>®</sup>** "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 **COMBIFORTE<sup>®</sup>** should be discontinued temporarily.

**IDENTIFICATION:**

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

**PRESENTATION:**

30, 60 and 90 capsules in 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:

October 2008

**NAME AND BUSINESS ADDRESS OF MANUFACTURER:**

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## VOUBILJET

**SKEDULERINGSSTATUS: voeding aan te vul (Wet 54/1972)**

**EIENDOMSNAAM (EN DOSEERVORM):**

**COMBIFORTE® kapsules**

**SAMESTELLING:**

Elke kapsule bevat 12,9 mg van 'n probiotiese mengsel bestaande uit *Lactobacillus acidophilus*, *Bifidobacterium bifidum* en *Bifidobacterium longum* (in 'n gevriesdroogde vorm), wat opbrengste in totaal nie minder nie as 1 miljard ( $10^9$ ) lewensvatbare selle, en 300 mg frukto-oligosakkaried.

**FARMAKOLOGIESE WERKING:**

**COMBIFORTE®** kapsules bevat 'n mengsel van gevriesdroogde melksuurbakteriëë naamlik *Lactobacillus acidophilus*, *Bifidobacterium bifidum* en *Bifidobacterium longum* wat natuurlike inwoners van die menslike ingewande is.

**COMBIFORTE®** word geadministreer om die normale intestinale *Lactobacillus* en *Bifidobacterium* wat vernietig word deur 'n breë spektrum antibiotika te herstel, en help sodoende met die beperking van die oorgroei van patogene organismes. Administrasie van hoë dosisse van hierdie bakteriëë help om diarree geassosieer met breë spektrum antibiotika te voorkom. Frukto-oligosakkaried verbeter menslike gesondheid deur selektiewe probiotika groei te ondersteun. Die gevolglike toename van inheemse derm bakteriëë, verhoog die bekampings van groei van patogene.

**INDIKASIE:**

**COMBIFORTE®** "Wanneer ingeneem op 'n gereelde basis, moet probiotika die mikrobiologiese balans verbeter of normaliseer in die menslike ingewande en sodoende die funksionering van die spysverteringsstelsel/ingewande verbeter"(50)

**KONTRA-INDIKASIE:**

Geen bekend

**DOSIS EN GEBRUIKSAANWYSINGS:**

Vir volwassenes:

**Behandelings Dosis:** 3 kapsules drie keer per dag geneem word met water (verkieslik op 'n leë maag, 30 minute voor etes), vir 1 tot 2 weke. In samewerking met antibiotika terapie, voortgaan met die behandeling vir ten minste een week na die voltooiing van die terapie word voorgestel.

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

Vir kinders:

1 tot 6 jaar oud: 1 kapsule per dag;

7 tot 14 jaar oud: 2 kapsules per dag;

Vir kinders bo 14 jaar: 'n volwassenes dosis word aanbeveel.

**NEWE-EFFEKTE EN SPESIALE VOORSORGMATREËLS:**

Groot dosisse kan los stoelgange veroorsaak in sommige individue.

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING:**

Los stoelgange waarna die administrasie van **COMBIFORTE®** tydelik gestaak word.

**IDENTIFIKASIE:**

Wit gelatien kapsules, wat wit tot roomkleurige korrel materiaal met 'n effense melksuur reuk bevat.

**AANBIEDING:**

30, 60 en 90 kapsules in draai dop houers.

**BERGINGSAAANWYSINGS:**

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

**HOU BUTE BEREIK VAN KINDERS.**

**DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:**

Oktober 2008

**NAAM EN BESIGHEIDSADRES VAN VERVAARDIGER:**

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