

PACKAGE INSERT

SCHEDULING STATUS: Nutritional supplement (Act 54/1972)

PROPRIETARY NAME (AND DOSAGE FORM):

KIDDIEFORTE[®] 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 (10⁹) viable cells, and 300 mg of a prebiotic, fructo-oligosaccharide, which selectively supports the growth of probiotic strains.

PHARMACOLOGICAL ACTION:

KIDDIEFORTE[®] 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[®] 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[®] "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[®]** 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

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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 patogeen 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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