

VAGIFORTE® PLUS PACKAGE INSERT

SCHEDULING STATUS: 0

PROPRIETARY NAME (AND DOSAGE FORM): VAGIFORTE® PLUS capsules and tablets

COMPOSITION: Each capsule contains 45 mg comprising *Lactobacillus acidophilus*, *Bifidobacterium bifidum* and *Bifidobacterium longum* (in a lyophilised form), which yield in total not less than 3 billion (3×10^9) viable cells. Each tablet contains 15 mg of *Lactobacillus acidophilus*, *Bifidobacterium bifidum* and *Bifidobacterium longum* (in a lyophilised form), which yield not less than 1 billion (10^9) viable cells.

PHARMACOLOGICAL ACTION: VAGIFORTE® PLUS capsules and tablets contain a mixture of lyophilised lactic acid bacteria namely, *Lactobacillus acidophilus*, *Bifidobacterium bifidum* and *Bifidobacterium longum* which are natural inhabitants of the human vagina and intestinal tract.

VAGIFORTE® PLUS is administered to restore and maintain the normal vaginal flora (mainly lactic acid bacteria) frequently destroyed by broad-spectrum antibiotics, the use of disinfectants, soaps and deodorants. Lactic acid bacteria control the overgrowth of pathogenic microorganisms in the human digestive tract and prevent their potential transfer to the uro-genital tract. Administration of high doses of these bacteria helps to prevent the development of vaginosis (bacterial vaginal infections) and of vaginitis (vaginal thrush caused by *Candida albicans*), frequently associated with the broad-spectrum antibiotic treatment.

INDICATIONS: VAGIFORTE® PLUS capsules and tablets are indicated primarily for the treatment of vaginal thrush induced by antibiotic treatment or the excessive use of strong soaps, disinfectants and deodorants, for the restoration of the bacterial flora occurring naturally in the human vagina and for the prevention of transfer of *Candida albicans* (a natural intestinal inhabitant) to the vagina. Some forms of vaginosis also respond to the treatment with **VAGIFORTE® PLUS**.

CONTRA-INDICATIONS: None known

DOSAGE AND DIRECTIONS FOR USE: One capsule to be taken once daily with water (preferably on an empty stomach, 30 minutes before breakfast). Complete the 5 day oral capsule course (before using the vaginal tablets). One vaginal tablet to be inserted into the vagina in the evening, before bedtime for the next 5 days. The full course can be repeated if necessary.

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

WARNING AND SPECIAL PRECAUTIONS: The 5 day oral capsule course must be completed before inserting the vaginal tablets for the next 5 days. This will alleviate any possible burning sensation or irritation of the vaginal mucosa in the event that the vaginal tablets are inadvertently used during the first 5 days of the course.

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

IDENTIFICATION: White and maroon capsules containing white to cream coloured, granular material with a slight lactic acid smell. White, long-oval tablets.

PRESENTATION: 5 white and maroon capsules, and 5 white tablets in a blister strip, packed in a unit carton.

STORAGE CONDITIONS: Store in a cool, dry place below 25°C.

KEEP OUT OF REACH OF CHILDREN.

DATE OF PUBLICATION OF THIS PACKAGE INSERT: July 2016

NAME AND BUSINESS ADDRESS OF MANUFACTURER:

CREATIVE CARE SOLUTIONS MEDICAL (Pty) Ltd, (Reg. No 2003/022808/07)

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VAGIFORTE® PLUS VOUBILJET

SKEDULERINGSSTATUS: 0

EIENDOMSNAAM (EN DOSEERVORM): VAGIFORTE® PLUS kapsules en tablette

SAMESTELLING: Elke kapsule bevat 45 mg wat bestaan uit *Lactobacillus acidophilus*, *Bifidobacterium bifidum* en *Bifidobacterium longum* (in 'n geliofiliseerde vorm), wat in totaal nie minder as 3 biljoen (3 x 10⁹) lewensvatbare selle, verskaf. Elke tablet bevat 10 mg *Lactobacillus acidophilus*, *Bifidobacterium bifidum* en *Bifidobacterium longum* (in 'n geliofiliseerde vorm), wat in totaal nie minder as 1 biljoen (10⁹) lewensvatbare selle, verskaf.

FARMAKOLOGIESE WERKING: VAGIFORTE® PLUS kapsules en tablette bevat 'n mengsel van geliofiliseerde melksuurbakterieë naamlik, *Lactobacillus acidophilus*, *Bifidobacterium bifidum* en *Bifidobacterium longum* wat natuurlik in die menslike vagina en dermkanaal voorkom. VAGIFORTE® PLUS word toegedien om die normale vaginale flora (hoofsaaklik melksuurbakterieë) wat dikwels deur breë-spektrum antibiotika, en die gebruik van ontsmettingsmiddels, sepe en deodorante vernietig word, te herstel en te onderhou. Melksuurbakterieë beheer die oormatige groei van patogene mikroörganismes in die menslike dermkanaal en verhoed hul potensieële oordraging na die urogenitale kanaal. Toediening van hoë dosisse van hierdie bakterieë help om die ontwikkeling van vaginose (bakteriële vaginale infeksies) en vaginitis (vaginale sproei wat deur *Candida albicans* veroorsaak word), wat dikwels met breë-spektrum antibiotika-behandeling geassosieer word, te voorkom.

INDIKASIES: VAGIFORTE® PLUS kapsules en tablette word primêr aangedui vir die behandeling van vaginale sproei wat deur antibiotiese behandeling of die oormatige gebruik van sterk sepe, ontsmettingsmiddels en deodorante geïnduseer word, vir die herstel van die bakteriële flora wat natuurlik in die menslike vagina voorkom en vir voorkoming van die oordrag van *Candida albicans* (wat natuurlik voorkom in die dermkanaal) na die vagina. Sommige vorms van vaginose reageer ook op behandeling met VAGIFORTE® PLUS.

KONTRA-INDIKASIES: Geen bekend nie.

DOSES EN GEBRUIKSAANWYSINGS: Een kapsule wat een keer daaglik met water geneem word (liefs op 'n leë maag, 30 minute voor ontbyt). Voltooi die 5-daagse orale kapsule-kursus (voordat die vaginale tablette gebruik word). Een vaginale tablet moet in die vagina ingevoer word in die aand, voor slapenstyd vir die volgende 5 dae. Die volle kursus kan indien nodig herhaal word.

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

WAARSKUWING EN SPESIALE VOORSORGMATREËLS: Die 5-daagse orale kapsule-kursus moet voltooi word voordat die vaginale tablette vir die volgende 5 dae ingevoer word. Dit sal enige moontlike brandende sensasie of irritasie van die vaginale slymvlies verlig ingeval die vaginale tablette per abuis tydens die eerste 5 dae van die kursus gebruik word.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Los stoelgang waarna die toediening van VAGIFORTE® PLUS kapsules en tablette tydelik gestaak moet word.

IDENTIFIKASIE: Wit en karmosynrooi kapsules, wat wit tot roomkleurige, granulére materiaal met 'n effense melksuurgeur bevat. Wit, lang ovale tablette.

AANBIEDING: 5 wit en karmosynrooi kapsules, en 5 wit tablette in 'n blaasverpakkingstrook, verpak in 'n eenheidskarton.

BERGINGSINSTRUKSIES: Bewaar in 'n koel, droë plek onder 25°C.

HOU BUITE BEREIK VAN KINDERS.

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