

Crèche Guard

COMPLETE PROBIOTIC SPRAY 25ml

SCHEDULING STATUS:

Complementary Medicine. Will be allocated upon registration.

PROPRIETY NAME AND DOSAGE FORM:

CRÈCHE GUARD COMPLETE PROBIOTIC Spray

COMPOSITION:

Active Ingredients:

Ingredients:	per ml
<i>Bifidobacterium longum</i>	3 billion CFU's
<i>Bifidobacterium bifidum</i>	
<i>Bifidobacterium lactis</i>	
<i>Lactobacillus acidophilus</i>	
<i>Lactobacillus rhamnosus</i>	
<i>Lactobacillus salivarius</i>	
<i>Lactobacillus reuteri</i>	

In-active Ingredients: Waglinol Caprylic, Aerosil 200, Stevioside, Strawberry Flavour

PHARMACOLOGICAL CLASSIFICATION:

Health Supplement – Probiotics D 11.10 (Other) Medicines acting on the gastro-intestinal tract.

PHARMACOLOGICAL ACTIONS:

A probiotic is a live microbial dietary supplement that beneficially affects the host by improving its intestinal microbial balance and exerting health affects beyond basic nutrition.

The lyophilised lactic acid bacteria *Lactobacillus rhamnosus* are beneficial bacteria that colonise the human intestinal tract and are normal inhabitants of a healthy intestine. *Lactobacillus* strains are most active in the small intestine, particularly in the ileum, whilst the *Bifidobacteria* strains are most active in the colon. Lactic acid bacteria also colonise the vagina, cervix and urethra.

Lactic acid bacteria are tolerant to bile and gastric acid and are therefore able to pass through the upper gastro-intestinal tract and colonise the small intestine and colon. Within the intestines these bacteria can adhere to the intestinal epithelium where they help restore the balance of the intestinal microflora, stimulate the production of antimicrobial compounds (such as acidolin, acidophilin, lactocidin and bacteriocin) which inhibit pathogenic micro-organisms, positively influence the immune system and assist in the production of vitamins. They also help complete the digestion of food components that were not digested in the small intestine, such as lactose in lactose intolerant individuals or fibres resistant to the digestive enzymes encountered in the small intestine. The metabolic end-products of their growth are organic acids (lactic and acetic acids) that lower the pH of the intestinal contents, creating conditions less desirable for harmful bacteria. *Bifidobacteria* have been proven to exert numerous beneficial effects including alleviation of lactose intolerance, alleviation of diarrhoea associated with antibiotic treatment, reduction of rotavirus-induced diarrhoea, reduced incidence of traveller's diarrhoea, reduction of candida colonisation and infection (thrush).

INDICATIONS:

When there is an intestinal imbalance such as during and after antibiotic therapy, diarrhoea associated with antibiotic use, infectious diarrhoea, including diarrhoea associated with rotavirus and *Clostridium difficile* infection, lactose intolerance, or constipation Crèche Guard Complete Probiotic Spray assists to restore and maintain the intestinal microflora.

Crèche Guard Complete Probiotic Spray may also assist the body in stimulating the immune system.

CONTRAINDICATIONS:

Crèche Guard Complete Probiotic Spray is contra-indicated in individuals who are hypersensitive to any of the ingredients.

WARNINGS AND SPECIAL PRECAUTIONS:

See CONTRAINDICATIONS.

Caution is advised if any hypersensitivity to the ingredients.

INTERACTIONS:

Consult your Doctor or Pharmacist when taking this supplement in together with other medication. If you experience discomfort or symptoms of overdose or hypersensitivity reactions while using Crèche Guard Complete Probiotic Spray we advise that you discontinue the use of this product immediately and if symptoms persist consult your health practitioner.

PREGNANCY AND LACTATION:

Can be used in pregnancy and lactation.

DOSAGE AND DIRECTION FOR USE:

Children over 1 year: Two sprays daily. Especially during and after antibiotic treatment. Administer 2-3 hours before or after antibiotics. Crèche Guard Complete Probiotic Spray does not need to be stored in the fridge. Shake well before use.

SIDE EFFECTS:

Probiotics are generally well tolerated at the recommended dosages. At dosages exceeding the recommended daily dose abdominal discomfort and flatulence may be experienced.

KNOWN SYMPTOMS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT:

If loose stools occur while using Crèche Guard Complete Probiotic Spray discontinue use for 24 hours.

IDENTIFICATION:

An oily liquid with suspended material having a strawberry taste.

PRESENTATION:

A 30 ml amber glass bottle with a metered spray insert, containing 25 ml of liquid equivalent to +80 sprays.

STORAGE INSTRUCTIONS:

Store in a cool, dry place at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

Will be allocated by the Council upon registration.

NAME AND BUSINESS ADDRESS OF APPLICANT:

Kenza Health (Pty) Ltd, 51 APD Office Park, Kelvin Street, Kya Sands, South Africa.
Customer Care: 0860 103 359 | www.crecheguard.co.za

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

July 2017

DISCLAIMER:

This medicine has not been evaluated by the Medicines Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease.

Crèche Guard

COMPLETE PROBIOTIC SPRAY 25ml

SKEDULERINGSSTATUS:

Sal toegeken word met registrasie.

EIENDOMSNAAM EN DOSEERVORM:

CRECHE GUARD COMPLETE PROBIOTIC Spray

SAMESTELLING:

Aktiewe bestanddele:

Bestanddele:	per ml
<i>Bifidobacterium longum</i>	3 miljard kfe
<i>Bifidobacterium bifidum</i>	
<i>Bifidobacterium lactis</i>	
<i>Lactobacillus acidophilus</i>	
<i>Lactobacillus rhamnosus</i>	
<i>Lactobacillus salivarius</i>	
<i>Lactobacillus reuteri</i>	

Onaktiewe bestanddele: Waglinol Caprylic, Aerosil 200, Stevioside, Aarbei geursel

FARMAKOLOGIESE KLASSIFIKASIE:

Gesondheidsaanvulling. Probiotics D 11.10 (Other) Medisyne wat op die spysverteringskanaal reageer.

FARMAKOLOGIESE AKSIES:

'n Probiotika is 'n lewendige mikrobiële diëet aanvulling wat voordelige invloed op die gasheer het, deur die spysverteringskanaal mikrobiese balans, en gesondheids effekte te verbeter, meer as wat basiese voeding bied.

Die gevriesdroogde melksuurbakterieë *Lactobacillus rhamnosus* is voordelige bakterie wat koloniseer in die menslike spysverteringskanaal en is normale inwoners van 'n gesonde derm. *Lactobacillus* stamme is die meeste aktief in die dunderm, veral in die ilcum, terwyl die *Bifidobacterië* stamme die meeste aktief is in die kolon. Melksuurbakterieë koloniseer ook in die vagina, serviks en uretra. Melksuurbakterieë is verdraagsaam teenoor gal en maagsuur en is dus in staat om deur die boonste gastro-intestinale kanaal te gaan en koloniseer die dunderm en kolon. Binne die ingewande het hierdie bakterieë die vermoë om te voldoen aan die derm epiteel, waar hulle help om die balans van die intestinale mikroflora te herstel, en stimuleer die produksie van antimikrobiële verbindings (soos acidolin, acidophilin, lactocidin en bacteriocines) waar patogeeniese mikro-organismes woon, wat die immuunstelsel positief beïnvloed en help met die produksie van vitamien. Hulle help ook om die vertering te voltooi van voedsel komponente wat nie verteer is in die dunderm nie, soos lactose, onverdraagsaamheid of vesel weerstand teen die verteringsensieme wat ons teëkom in die dunderm. Die metaboolse eindprodukte van hul groei is organiese sure (melksuur en asynsuur) wat die pH van die intestinale inhoud verlaag, en skep minder wenslike omstandighede vir skadelike bakterieë. *Bifidobacterium* het talle voordelige effekte bewys, insluitend verligting van laktose onverdraagsaamheid, verligting van diarree wat verband hou met antibiotika behandeling, die vermindering van rotavirus veroorsaakte diarree, vermindering van voorkom van die reisigers diarree, en die vermindering van candida kolonisasie en infeksie (sproei).

INDIKASIES:

Wanneer daar 'n spyverteringsflora wanbalans is, soos na 'n antibiotika behandeling, diarree wat verband hou met antibiotika gebruik, aansteeklike diarree en diarree wat verband hou met rotavirus en *Clostridium difficile* infeksie, laktose onverdraagsaamheid, of hardlywigheid, help "Creche Guard Complete Probiotic Spray" om die intestinale mikroflora te herstel en in stand te hou. "Creche Guard Complete Probiotic Spray" kan ook die liggaam help in die stimulering van die immuunstelsel.

KONTRA-INDIKASIES:

Creche Guard Complete Probiotic Spray het kontra indikasies vir persone wat hipersensitief is vir enige van die bestanddele.

WAARSKUWINGS EN SPESIALE VOORSORGMATREËLS:

Creche Guard Complete Probiotic Spray" het kontra indikasies vir persone wat hipersensitief is vir enige van die bestanddele.

INTERAKSIES:

Raadpleeg jou dokter of apteker as jy hierdie aanvulling saam met ander medikasie vir jou kind wil gebruik. As jou kind ongemak ervaar, of simptome van oordosering of hipersensitiewe reaksies toon terwyl "Creche Guard Complete Probiotic Spray" gebruik word, beveel ons aan dat u dadelik die gebruik van die produk staak, en as die simptome aanhou, spreek u gesondheid praktisyen.

SWANGERSKAP EN BORSVOEDING:

Kan tydens swangerskap en borsvoeding gebruik word.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Daar is geen bekende simptome van oordosering nie.

As u kind enige onaangename simptome ervaar, staak dadelik die gebruik van "Creche Guard Complete Probiotic Spray", en as die simptome volhou, kontak jou gesondheidsorg praktisyen dadelik of kontak die vergiftigings informasie sentrum.

IDENTIFIKASIE:

'n Olierige vloeistof met gesuspendeerde materiaal met 'n aarbei smaak.

AANBIEDING:

'n 30ml bruin glas bottel met 'n spuit meter insetsel, wat 25 ml vloeistof bevat gelykstaande aan ±80 spuite.

BERGINGSINSTRUKSIES:

Bewaar in 'n koel, droë plek teen of benede 25 °C.

HOU BUITE BEREIK VAN KINDERS.

REGISTRASIENOMMER:

Sal toegeken word met registrasies deur Raad.

NAAM EN BESIGHEIDSADRES VAN HOUER VAN REGISTRASIESERTIFIKAAT:

Kenza Health (Edms) Bpk, ADP Kantoorpark no 51, Kelvin Straat, Kya Sands, Suid-Afrika. Kliëntediens: 0860 103 359 | www.crecheguard.co.za

DATUM VAN PUBLIKASIE VAN VOUILJET:

Julie 2017

VRYWARING:

Hierdie medisyne is nie deur die Medisynebeheerraad geëvalueer nie. Hierdie medisyne is nie bedoel om enige siekte te diagnoseer, behandel, genees of voorkom nie.