

# Crèche Guard

## BABY PROBIOTIC DROPS 20ml

**SCHEDULING STATUS:**

Unscheduled

**PROPRIETY NAME AND DOSAGE FORM:**

CRECHE GUARD L.REUTERI PROBIOTIC DROPS

**COMPOSITION:**

Nutritional information per dose:

**Active Ingredients:**

<b>Each ml contains 3 billion CFU's</b>
<i>Lactobacillus reuteri</i> SD-5865 750 million CFU/ml
<i>Bifidobacterium longum</i> spp. <i>infantis</i> Bi-26 750 million CFU/ml
<i>Lactobacillus rhamnosus</i> GG 750 million CFU/ml
<i>Lactobacillus salivarius</i> Ls-33 750 million CFU/ml

**PHARMACOLOGICAL CLASSIFICATION:**

Health Supplement D. 32.16 Other.

**DISCIPLINE OF MEDICINE:**

Probiotic Health supplement.

**PHARMACOLOGICAL ACTION:**

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.

Crèche Guard L.Reuteri Probiotic Drops contains *Lactobacillus reuteri*, *Lactobacillus salivarius*, *Lactobacillus rhamnosus* and *Bifidobacterium infantis* to balance the microflora of the complete GALT.

Crèche Guard L.Reuteri Probiotic Drops have been specifically formulated to support your child's immune system by balancing the intestinal microflora.

*Lactobacillus reuteri* is a probiotic, which naturally occurs in the gastrointestinal tract. It colonizes the stomach, small and large intestine. The lyophilised lactic acid bacteria *Lactobacillus rhamnosus* are beneficial bacteria that colonize 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* species are most active in the colon. Lactic acid bacteria also colonize 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 colonize the small intestine and colon. Within the intestines these bacteria have the ability to 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 fibers 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 candidal 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 L. Reuteri Probiotic Oral Drops assists to restore and maintain the intestinal microflora. Crèche Guard L. Reuteri Probiotic Oral Drops may also assist the body in stimulating the immune system.

**CONTRA-INDICATIONS:**

Crèche Guard L. Reuteri Probiotic Oral Drops is contra-indicated in individuals who are hypersensitive to any of the ingredients.

**DOSAGE AND DIRECTIONS FOR USE:**

5 drops daily. Especially during and after antibiotic treatment. Administer 2-3 hours before or after antibiotics. Crèche Guard Probiotic L. Reuteri Oral Drops does not need to be stored in the fridge. Shake well before use.

**SIDE EFFECTS AND SPECIAL PRECAUTIONS:**

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

**IDENTIFICATION:**

An oily liquid with suspended material.

**PRESENTATION:**

A 30 ml amber glass bottle with a dropper insert, containing 20ml of liquid equivalent to +100 dosages.

**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:**

June 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.

# Créche Guard

## BABY PROBIOTIC DROPS 20ml

### SKEDULERINGSSTATUS:

Ongeskeduleerd.

### EIENDOMSNAAM EN DOSEERVORM:

CRECHE GUARD L.REUTERI DROPS

### SAMESTELLING:

#### Aktiewe bestanddele:

<b>Elke ml bevat 3 biljoen CFU's</b>
<i>Lactobacillus reuteri</i> SD-5865 750 million CFU/ml
<i>Bifidobacterium longum</i> spp. <i>infantis</i> Bi-26 750 million CFU/ml
<i>Lactobacillus rhamnosus</i> GG 750 million CFU/ml
<i>Lactobacillus salivarius</i> Ls-33 750 million CFU/ml

### FARMAKOLOGIESE KLASSIFIKASIE:

Gesondheidsaanvulling D.32.16 Ander.

### DISSIPLINE VAN GENEESKUNDE:

Probiotiese gesondheidsaanvulling.

### FARMAKOLOGIESE AKSIES:

'n Probiotika is 'n lewendige mikrobiële diëet aanvulling wat voordelige invloed op die gasheer het, deur die derm mikrobiese balans, en gesondheids effekte te verbeter, meer as wat basiese voeding bied. Creche Guard L.Reuteri Probiotic Drops (Druppels) bevat *Lactobacillus reuteri*, *Lactobacillus salivarius*, *Lactobacillus rhamnosus* en *Bifidobacterium infantis* om die mikroflora van die volledige GALT te balanseer.

Creche Guard L.Reuteri Drops (Druppels) is spesifiek geformuleer om jou kind se immuun stelsel te ondersteun deur die ingewande mikroflora te balanseer

*Lactobacillus reuteri* is 'n probiotikum wat natuurlike voorkom in die spysverteringskanaal. Dit koloniseer die maag, dunderm en dikderm.

Die gevriesdroogde melksuurbakterieë *Lactobacillus rhamnosus* is voordelige bakterieë wat koloniseer in die menslike derm en is normale inwoners van 'n gesonde derm. *Lactobacillus* spesies is die meeste aktief in die dunderm, veral in die ilium, terwyl die *Bifidobacterië* spesies die meeste aktief is in die kolon. Melksuurbakterieë koloniseer ook in die vagina, serviks en uretra.

Melksuurbakterieë is ongevoelig 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 patogeniese 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 laktose in laktose onverdraagsaamheid of vesel weerstandig teen die verteringsensieme wat ons teëkom in die dunderm. Die metabolisme eindprodukte van hul groei is organiese sure (melksuur en bottersuur) wat die pH van die intestinale inhoud verlaag, en skep minder wenslike omstandighede vir skadelike bakterieë.

*Bifidobacterië* 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, verminder die voorkom van die reisigers diarree, en die vermindering van kandidale kolonisasie en infeksie (sproei).

### INDIKASIES:

Wanneer daar 'n derm 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 L.Reuteri Probiotic Oral Drops" om die intestinale mikroflora te herstel en in stand te hou.

"Creche Guard L.Reuteri Probiotic Oral Drops" kan ook die liggaam help in die stimulering van die immuunstelsel.

### KONTRA-INDIKASIES:

"Creche Guard L.Reuteri Probiotic Oral Drops" het kontra indikasies vir persone wat hipersensitief is vir enige van die bestanddele.

### DOSES EN GEBRUIKSAANWYSINGS:

5 druppels daaglik. Veral gedurende en na antibiotika behandeling. Toediening 2-3 uur voor of na antibiotika. "Creche Guard L.Reuteri Probiotic Oral Drops" hoef nie in die yskas gestoor te word nie. Skud goed voor gebruik.

### NEWE EFFEKTE EN SPESIALE VOORSORGMAATREELS:

Probiotika word oor die algemeen goed verdra by die gebruik van die aanbevole dosisse. By dosisse wat die aanbevole daaglikse dosis oorskry, kan abdominale ongemak en winderigheid ervaar word.

### BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

As los stoelgang voorkom terwyl "Creche Guard L.Reuteri Probiotic Oral Drops" gebruik word, staak gebruik vir 24 uur.

### IDENTIFIKASIE:

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

### AANBIEDING:

'n 30ml bruin bottle met 'n dropper insetel, wat 20ml vloeistof bevat gelykstaande aan ±100 dosisse.

### BERGINGSINSTRUKSIES:

Bewaar in 'n koel, droë plek teen of benede 25 °C. **HOU BUTTE 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 VOUJLJET:

Junie 2017

### VRYWARING:

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