

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

CRECHE GUARD BABY COMPLETE PROBIOTIC DROPS

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	Per 1ml
Lactobacillus reuteri SD-5865	3 billion CFU's (Colony forming units)
Bifidobacterium longum spp. Infantis Bi-26	
Lactobacillus rhamnosus GG	
Lactobacillus salivarius LS-33	

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

White to cream coloured granules suspended in oil with smell and taste of strawberries.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

CRECHE GUARD BABY COMPLETE PROBIOTIC DROPS provide essential probiotics for the maintenance of good health in children.

When ingested on a regular basis, probiotics should improve or normalize the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut.

4.2 Posology and method of administration

Infants and children 0-3 years: Administer five drops daily into the mouth, or as directed by a healthcare provider.

Shake well before use.

4.3 Contraindications

Do not use CRECHE GUARD BABY COMPLETE PROBIOTIC DROPS:

- if you are hypersensitive to any of the ingredients, including the excipients.

4.4 Special warnings and precautions for use

None.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies were performed on CRECHE GUARD BABY COMPLETE PROBIOTIC DROPS. The following interactions are noted in the monographs of the probiotic strains:

- Antibiotics: Separate administration of antibiotics and probiotics by at least 2 hours as simultaneous administration may kill a significant number of the probiotics.
- Immunosuppressants: theoretically, probiotics may cause infection in patients taking medicines to suppress the immune system.

4.6 Undesirable effects

Oral probiotics are generally well tolerated.

Possible side effects include gastrointestinal discomfort (nausea, vomiting, abdominal pain, bloating, rumbling, burping, dyspepsia, or diarrhoea), skin rash, itching.

4.7 Overdose

There is insufficient reliable information available about the toxicology of probiotics.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Health Supplement

D34.9 Probiotics

5.2 PHARMACOLOGICAL ACTION

When ingested on a regular basis, probiotics should improve or normalize the microbial balance in the human intestines and thereby improve the functioning of the digestive tract/gut.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Silicon dioxide 0,3%, strawberry flavour and medium chain triglyceride oil.

Alcohol and Tartrazine free

6.2 Incompatibilities

Unknown

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C. Keep bottle tightly closed and protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

CRECHE GUARD BABY COMPLETE PROBIOTIC DROPS is available in bottles containing 20ml.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd, 15E Riley Road, Bedfordview, 2007

Tel: (011) 087 0000

www.inovapharma.co.za

8 REGISTRATION NUMBER

To be allocated.

This unregistered medicine has not been evaluated by the South African Health Products Regulatory Authority for its quality, safety or intended use.

9 DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

September 2020