

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

CRECHE GUARD BABY PROBIOTIC MULTIVITAMIN SPRAY

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	Per 1ml
Probiotics	
HOWARU Bifidobacterium lactis	3 billion CFU's (Colony forming units)
Bifidobacterium longum sp. BI-05	
Vitamins	
Vitamin E (as alpha-tocopherol)	4,6 mg
Vitamin B3 (as nicotinamide)	2 mg
Vitamin B1 (as thiamine)	1 mg
Vitamin B2 (as riboflavin)	1 mg
Vitamin B6 (as pyridoxine)	0,4 mg
Folic acid	80 µg
Vitamin D3 (as cholecalciferol)	400 IU (10 µg)
Vitamin B12 (as cyanocobalamin)	5 µg

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 PROBIOTIC MULTIVITAMIN SPRAY provides essential vitamins and minerals 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 from 1 year: Spray 2 sprays daily in the mouth

Shake well before use.

4.3 Contraindications

Do not use CRECHE GUARD BABY PROBIOTIC MULTIVITAMIN SPRAY in patients who are:

- hypersensitive to any of the ingredients, including the excipients.

4.4 Special warnings and precautions for use

Use in children under the age of 1 year is at the discretion of the healthcare professional.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies were performed on CRECHE GUARD BABY PROBIOTIC MULTIVITAMIN SPRAY. The following interactions are noted in the monographs of the active ingredients:

- 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

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. Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Health Supplement

D34.12 Multiple substance formulation

5.2 PHARMACOLOGICAL ACTION

- The B Vitamins help to metabolise carbohydrates, fats and proteins, contribute to normal psychological function, normal functioning of the nervous system, maintenance of normal mucous membranes, maintenance of normal skin and the reduction of tiredness and fatigue.
- Vitamin D contributes to normal immune function, maintenance of normal muscle function, cell division, and the development and maintenance of strong bones and teeth.
- Vitamin E functions as a tissue antioxidant thereby maintaining healthy cells.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

Contains natural sweetener Stevia 0,13 mg/ml

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 PROBIOTIC MULTIVITAMIN SPRAY is available in bottles containing 25ml.

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

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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

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