

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

CRÈCHE GUARD PROBIOTIC IMMUNE CHOC BARS (chews)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	Per 5 g chew
HOWARU [®] Bifidobacterium lactis HN019 [™]	2 billion Colony Forming Units
Calcium (from calcium carbonate)	120 mg
Vitamin C (from sodium ascorbate)	40 mg
Vitamin B3 (as nicotinamide)	8 mg
Vitamin E (as dl-alpha-tocopheryl acetate)	6 mg
Iron (from ferric pyrophosphate)	3,5 mg
Pantothenic acid (from calcium-d-pantothenate)	3 mg
Vitamin B2 (as riboflavin)	0,7 mg
Vitamin B6 (from pyridoxine hydrochloride)	0,7mg
Vitamin B1 (from thiamine mononitrate)	0,55 mg
Vitamin A (as retinyl acetate)	400 ug
Folic acid	199 ug
Iodine (from potassium iodide)	75 ug
Biotin	25 ug
Vitamin D (as cholecalciferol)	5 ug
Vitamin B12 (as cyanocobalamin)	1,25 ug

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Brown coloured chocolate bars with the look, taste and smell of chocolate.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

CRÈCHE GUARD PROBIOTIC IMMUNE CHOC BARS provide essential vitamins and minerals for the maintenance of good health and to support normal growth and development in children.

CRÈCHE GUARD PROBIOTIC IMMUNE CHOC BARS contain HOWARU[®] Bifidobacterium lactis HN019[™] which is a probiotic. 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

Children 2 years and older: Chew one chocolate bar daily after food, or as recommended by a healthcare provider.

4.3 Contraindications

- Patients who are hypersensitive to any of the ingredients, including the excipients.
- Children under the age of 2 years.

4.4 Special warnings and precautions for use

CRÈCHE GUARD PROBIOTIC IMMUNE CHOC BARS contain sugar. This may have an effect on the control of blood sugar in patients with diabetes mellitus.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies were performed.

4.6 Fertility, pregnancy and lactation

CRÈCHE GUARD PROBIOTIC IMMUNE CHOC BARS is not recommended for use during pregnancy and lactation as safety has not been demonstrated.

4.7 Effects on ability to drive and use machines

The effects on ability to drive and use machines has not been studied.

4.8 Undesirable effects

No data available.

4.9 Overdose

Symptoms of overdosage include stomach upset, nausea, diarrhoea or constipation.

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.
- Calcium contributes to normal muscle function and helps in the development of healthy bones and teeth.
- Iodine contributes to normal cognitive function, nervous system function, and to normal growth and development.
- Iron contributes to normal formation of red blood cells and haemoglobin and their proper function, normal oxygen transport in the body, cognitive function and immune system function.
- Vitamin C is an antioxidant which contributes to cell protection from free radical damage, helps in the development and maintenance of bones, cartilage, teeth and gums and helps with connective tissue formation.
- 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.
- Zinc is an essential element which contributes to the maintenance of immune function and the maintenance of normal skin.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cocoa butter, cocoa mass, cocoa solids, dry milk solids, whole milk powder.

Contains sugar: 2,4 g per chew tablet

6.2 Incompatibilities

Unknown

6.3 Shelf life

15 months

6.4 Special precautions for storage

Store at or below 25 °C.

Store chews in carton and protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

CRÈCHE GUARD PROBIOTIC IMMUNE CHOC BARS is available in packs of 30.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF THE CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd
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8 REGISTRATION NUMBER

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 2021