

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

CRECHE GUARD BABY IMMUNE MULTIVITAMIN SYRUP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredient	Per 2,5ml
Vitamin C (as ascorbic acid)	16,4 mg
Vitamin B3 (as nicotinamide)	3,6 mg
Vitamin E (as alpha-tocopherol)	2,7 mg
Zinc (from zinc glycinate) Glycine (from zinc glycinate) 0,879 mg	2,5 mg
Vitamin B5 (as calcium pantothenate)	1,1 mg
Vitamin B6 (as pyridoxine)	0,5 mg
Vitamin B2 (as riboflavin)	0,3 mg
Vitamin B1 (as thiamine)	0,3 mg
Biotin	54,5 ug
Folic acid	49,8 ug
Vitamin B12 (s cyanocobalamin)	0,2 ug
Vitamin A (as retinol)	750 IU
Vitamin D3 (as cholecalciferol)	200 IU

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Yellow coloured syrup with smell and taste of cherries.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

CRECHE GUARD BABY IMMUNE MULTIVITAMIN SYRUP is a health supplement which provides essential vitamins and minerals for the maintenance of good health and to support normal growth and development in children.

4.2 Posology and method of administration

Children 1 – 3 years: Take half a medicine measure (2,5 ml) daily, or as directed by your healthcare provider.
Shake well before use.

4.3 Contraindications

Do not use CRECHE GUARD BABY IMMUNE MULTIVITAMIN SYRUP:

- In patients who are hypersensitive to any of the ingredients, including the excipients.

4.4 Special warnings and precautions for use

- CRECHE GUARD BABY IMMUNE MULTIVITAMIN SYRUP contains sorbitol which may have an effect on the glycaemic control of children with *diabetes mellitus*.
- Children with the rare hereditary condition of sorbitol intolerance should not take this product.
- Use in children under the age of 1 year is at the discretion of a healthcare professional.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies were performed on CRECHE GUARD BABY IMMUNE MULTIVITAMIN SYRUP.

4.6 Undesirable effects

Possible side effects are gastrointestinal discomfort (nausea, vomiting, heartburn, abdominal pain, bloating, dyspepsia, diarrhoea, constipation).

4.7 Overdose

Symptoms of overdosage include severe 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

Vitamin C:

- Contributes to iron absorption from food.
- Helps to metabolise fats and proteins.
- Contributes to cell protection from free radical damage and oxidative stress.
- Contributes to normal collagen formation for the normal function of blood vessels, bones, cartilage, gums, skin and teeth.
- Contributes to normal energy-yielding metabolism.
- Contributes to normal functioning of the nervous system.
- Contributes to normal psychological function.
- Contributes to the normal functioning of the immune system.
- Contributes to the reduction of tiredness and fatigue.
- Helps in connective tissue formation.
- Contributes to wound healing.
- An antioxidant for the maintenance of good health.

B Vitamins including Biotin:

- Help to metabolise carbohydrates, fats and proteins.
- Contribute to normal psychological function.
- Contribute to normal functioning of the nervous system.
- Help with maintenance of normal mucous membranes, maintenance of normal skin.
- Contribute to normal growth and development.
- Help with the reduction of tiredness and fatigue.
- A factor in the maintenance of good health.

Vitamin E:

- Functions as a tissue antioxidant which contributes to the protection of cells from oxidative stress.
- A factor in the maintenance of good health.

Folic acid:

- Helps to form red blood cells and helps the body metabolize proteins.

Zinc:

- Contributes to the maintenance of immune function.
- Contributes to the maintenance of normal skin, nails and hair.
- Contributes to normal acid-base metabolism.
- Contributes to normal cognitive function.
- Contributes to normal DNA synthesis.
- Contributes to normal metabolism of Vitamin A.
- Contributes to the maintenance of normal bones.
- Contributes to the maintenance of normal vision.
- Contributes to cell protection from free radical damage and oxidative stress.

Vitamin A:

- Contributes to the maintenance of normal vision.
- Contributes to the development and maintenance of night vision.
- Has a role in the process of cell division.
- Contributes to the maintenance of normal skin, normal mucous membranes and normal iron metabolism.

- Contributes to the normal functioning of the immune system.
- Contributes to the development and maintenance of bones and teeth.
- A factor in the maintenance of good health.

Vitamin D:

- Helps in the absorption and use of calcium and phosphorus.
- Contributes to normal cell division.
- Contributes to normal blood calcium levels.
- Contributes to the maintenance and development of strong bones and teeth.
- Contributes to the maintenance of normal muscle function.
- Contributes to the normal functioning of the immune system.
- Has a role in the process of cell division.
- A factor in the maintenance of good health.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid, glycerine, maltodextrin, natural cherry flavour, sodium carboxymethyl cellulose and water.

Contains sugar: sorbitol 1,86 g/2,5 ml

Preservatives: potassium sorbate 0,036 % (m/v),
sodium benzoate 0,048 % (m/v)

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 IMMUNE MULTIVITAMIN SYRUP is available in bottles containing 100ml.

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

August 2021