

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

ZINIUM JUNIOR (syrup)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	Per 5 ml
Zinc citrate 16,2 mg providing zinc elemental	5 mg
Ascorbic acid 33,3 mg providing vitamin C	33 mg
Vitamin D3 2,5 mg Providing cholecalciferol	250 IU

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Clear green liquid with a cream soda flavour and smell.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

ZINIUM JUNIOR provides immune support, supports brain health and helps maintain healthy skin.

4.2 Posology and method of administration

Children 1 – 3 years: Give one medicine measure (5 ml) daily, or as directed by a healthcare provider.

Children 4 – 8 years: Give two medicine measures (10 ml) daily, or as directed by a healthcare provider.

Children 9 – 13 years: Give four medicine measures (20 ml) daily, or as directed by a healthcare provider.

Shake the bottle before use.

4.3 Contraindications

Hypersensitivity to any of the active or inactive ingredients.

Children under 1 year of age.

4.4 Special warnings and precautions for use

ZINIUM JUNIOR contains sucrose, sorbitol and mannitol. This may have an effect on the glycaemic control of patients with diabetes mellitus.

Patients with the rare hereditary condition of sorbitol intolerance should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies were performed on ZINIUM JUNIOR.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy or lactation has not been established.

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

Possible side effects include:

- nausea,
- vomiting,
- metallic taste in the mouth,
- stomach cramps,
- heartburn, and
- indigestion.

4.9 Overdose

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

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 macronutrient metabolism.
- Contributes to normal metabolism of Vitamin A.
- Contributes to the maintenance of normal bones.
- Contributes to the maintenance of normal vision.
- Contributes to the maintenance of normal testosterone levels in the blood.
- Contributes to cell protection from free radical damage and oxidative stress.
- Has a role in the process of cell division
- Contributes to connective tissue formation
- Helps the body to metabolise carbohydrates, fats and proteins
- A factor in the maintenance of good health.

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.

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, cream soda flavour, green apple deep colourant, xanthan gum.

Contains sugar: glucose 2 g, sorbitol 994 mg and mannitol 114 mg

Preservatives: sodium benzoate 0,027 %, potassium sorbate 0,013 %

6.2 Incompatibilities

Unknown

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C.

Protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

200ml white plastic bottles.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd,
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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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