

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

ZINIUM INFANT DROPS (liquid)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	Per 1ml
Zinc citrate 6,5 mg providing zinc elemental	2 mg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Clear colourless odourless liquid with a sweet taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

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

4.2 Posology and method of administration

Children 0 - 1 year: Give 1 ml daily, as directed by a healthcare provider. Shake the bottle before use.

4.3 Contraindications

Hypersensitivity to any of the active or inactive ingredients.

4.4 Special warnings and precautions for use

ZINIUM INFANT DROPS contain 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 INFANT DROPS.

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
D34.7 Minerals

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water.

Contains sugar: sorbitol 209 mg, mannitol 24 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

30ml amber glass bottle with a dropper.

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

August 2021