

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

FLUGON FIZZY KIDZ (effervescent tablets)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredient	Per tablet
<i>Sambucus Nigra</i> (Elderberry) [fruit extract 4 %]	160 mg
<i>Pelargonium Sidoides</i> SPE60 (Pelargonium) [root extract]	30 mg
Vitamin C (as ascorbic acid 97 %)	150 mg
Zinc Gluconate 4 mg Providing Zinc elemental	0,52 mg
Vitamin D3 (as cholecalciferol)	500 IU
Biotin	150 µg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Light purple, mottled, round, flat tablet with characteristic grape flavour

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

FLUGON FIZZY KIDZ supports the immune system and helps alleviate cough, sore throat and a blocked or runny nose.

4.2 Posology and method of administration

The recommended dose is as follows:

At the first sign of colds and flu:

Children 4 - 12 years:

Take 1 tablet dissolved in water twice daily.

Daily immune system support:

Children 4 - 12 years:

Take 1 tablet dissolved in water daily.

Wait for effervescence to subside before drinking.

4.3 Contraindications

- Hypersensitivity to any of the active or inactive ingredients contained in FLUGON FIZZY.
- Children under the age of 4 years.

4.4 Special warnings and precautions for use

Due to the immunostimulant nature of the active ingredients, caution is advised in patients suffering from an auto-immune disease.

Pelargonium contains coumarins which may potentiate bleeding. Caution is advised in patients with a bleeding disorder.

Contains isomalt which may have an effect on the glycaemic control of children with *diabetes mellitus*.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed on FLUGON FIZZY KIDZ. The below interactions are noted in the literature on the active ingredients:

- Blood thinning medicines: Pelargonium contains coumarins which may potentiate bleeding.
- Immunosuppressant medicines: Pelargonium possesses immunostimulant properties and this may interfere with the action of medicines used to suppress the immune system, for example, medicines used for auto-immune conditions such as rheumatoid arthritis, systemic lupus erythematosus (SLE/lupus), etc.

4.8 Undesirable effects

Possible side effects include gastrointestinal discomfort (nausea, diarrhoea, constipation, vomiting, abdominal pain, stomach upset, heartburn), headache, dizziness, light-headedness, nose bleeds, and slight increases in body temperature and pulse.

Allergic reactions, most commonly presenting as skin rash or shortness of breath, have been reported in clinical trials with Pelargonium and Elderberry.

4.9 Overdose

Symptoms of overdosage include gastrointestinal irritation (nausea, diarrhoea, constipation, vomiting, abdominal pain, stomach upset and/or heartburn). Overdosage of Pelargonium may potentiate bleeding. Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine: Discipline Specific Traditional Claims - D33.7 Combination Product

5.2 PHARMACOLOGICAL ACTION

- Elderberry and Pelargonium have immunostimulant properties which help support the body's immune system.
- Vitamin C is an antioxidant which protects cells from free radical damage and contributes to normal immune function. It helps to metabolize fats and proteins, contributes to iron absorption from food, contributes to normal collagen formation for the normal function of blood vessels, bones, gums, teeth, skin and cartilage, assists with normal functioning of the nervous system, normal psychological function, reduction of tiredness and fatigue, connective tissue formation and wound healing.
- Zinc is an antioxidant which contributes to the protection of cells from oxidative stress, maintenance of immune function, cognitive function, normal vision, and normal skin, hair and bones. It contributes to DNA synthesis, acid-base metabolism, normal fertility and reproduction, normal testosterone levels, macronutrient metabolism, connective tissue formation, plays a role in the process of cell division and helps the body metabolize carbohydrates, fats and proteins.
- Biotin helps the body to metabolise carbohydrates, fats and proteins, contributes to normal functioning of the nervous system, normal psychological function, maintenance of mucous membranes and maintenance of normal skin and hair.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid, grape colouring, magnesium stearate, polyethylene glycol, sodium bicarbonate and silicon dioxide.

Contains sugar: isomalt 612 mg/tablet

Contains sweeteners: Sucralose 25 mg/tablet

6.2 Incompatibilities

Unknown

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C. Keep tube tightly closed and protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

Tubes containing 12 tablets.

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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