

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

FLUGON THROAT ORAL SPRAY

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredient	Per 1 ml
<i>Pelargonium Sidoides</i> SPE60 (Pelargonium) [root extract]	10 mg
<i>Sambucus Nigra</i> (Elderberry) [fruit extract 36:1]	5,6 mg
<i>Punica Granatum</i> (Pomegranate) [seed extract 50:1]	4 mg
Zinc (as Zinc Gluconate)	2,5 mg

Preservatives: Potassium sorbate 0,035 % m/v

Sodium benzoate 0,045 % m/v

Contains sugar: sorbitol 0.59 g/ml

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Red to brown coloured syrup with a sweet fruity flavour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

FLUGON THROAT ORAL SPRAY helps alleviate a sore throat, and throat and mouth irritations.

4.2 Posology and method of administration

The recommended dose is as follows:

Adults and children 12 years and older: 6 – 8 sprays into the mouth six times a day

Children 6 – 12 years old: 2 – 4 sprays into the mouth six times a day

Children 2 – 6 years old: 2 sprays into the mouth six times a day

4.3 Contraindications

- Hypersensitivity to any of the active or inactive ingredients contained in FLUGON THROAT ORAL SPRAY.
- Children under the age of 2 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 sorbitol which 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 product.

4.5 Interaction with other medicines and other forms of interaction

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

- Antidiabetic medicines: concomitant use of Elderberry with diabetes medicines may increase the risk of hypoglycaemia.
- Blood thinning medicines: Pelargonium contains coumarins which may potentiate bleeding.
- Antihypertensive medicines: Pomegranate may lower blood pressure.
- Immunosuppressant medicines: Pelargonium and Elderberry possess immunostimulant properties and this may interfere with the action of medicines used to suppress the immune system, for example, medicines used for autoimmune conditions such as rheumatoid arthritis, systemic lupus erythematosus (SLE/lupus), etc.

4.6 Fertility, pregnancy and lactation

FLUGON THROAT ORAL SPRAY is not suitable for use during pregnancy and while breastfeeding at the recommended dosage. The effects on fertility have not been studied.

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 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 Pomegranate. Allergic reactions involving swelling of the face and/or tongue and nasal congestion have been reported in patients taking Pomegranate.

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 Medicines: Discipline Specific traditional claims

D33.7 Combination product

5.2 PHARMACOLOGICAL ACTION

- Pelargonium possesses immunostimulant properties which helps support the immune system.
- Elderberry has antioxidant and immunostimulant effects.
- Pomegranate contains Vitamin C which helps support the immune system.
- Zinc is an essential mineral which contributes to the maintenance of immune function.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carmellose sodium, citric acid, maltodextrin.

Preservatives: Potassium sorbate 0,035 % m/v; sodium benzoate 0,045 % m/v

Contains sugar: sorbitol 0.59 g/ml

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

Bottles containing 50ml.

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

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