

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

FLUGON HOT LEMON (sachets)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredient	Per sachet
Methylsulfonyl methane (MSM)	1000 mg
<i>Echinacea Purpurea</i> (Echinacea) [root extract 4:1]	240 mg
<i>Pelargonium Sidaoides SPE 60</i> (Pelargonium) [root extract]	60 mg
<i>Citrus Sinensis L.</i> (Citrus Bioflavonoids) [fruit extract 13 %]	5 mg
Vitamin C (as ascorbic acid)	200 mg
Zinc gluconate 2,5 mg providing zinc elemental	0,3 mg
Selenium (from selenium glycinate 0,2 %)	10 ug
Vitamin D3 (as cholecalciferol)	150 IU

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

White to off-white powder and granule blend with a characteristic menthol and lemon taste and smell.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

FLUGON HOT LEMON helps with immune support throughout the year, and relieves body aches/chills, cough, sore throat and a blocked or runny nose associated with colds and flu.

4.2 Posology and method of administration

The recommended dose is as follows:

Adults and children over 12 years:

Drink one sachet dissolved in a glass of warm water, three times a day.

Consult a healthcare provider if symptoms do not improve after 5 days.

4.3 Contraindications

- Hypersensitivity to any of the active or inactive ingredients contained in FLUGON HOT LEMON.
- Patients allergic to sulphur should not take FLUGON HOT LEMON.
- Children under the age of 12 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 patients with *Diabetes Mellitus*. Patients with rare hereditary conditions such as fructos intolerance, glucose-galactose mal-

absorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

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

- Blood thinning medicines: Pelargonium contains coumarins which may potentiate bleeding.
- Cytochrome P450 substrates: Echinacea may inhibit the cytochrome P450 enzymes and inhibit the metabolism of concurrent medicines.
- Immunosuppressant medicines: Pelargonium and Echinacea possess 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.

4.6 Fertility, pregnancy and lactation

The safety has not been established during pregnancy or lactation. 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 Echinacea.

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.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Discipline-Specific Traditional Claims. D33.7 Combination product.

5.2 PHARMACOLOGICAL ACTION

- Methylsulfonyl methane has anti-allergy properties and may be used for relief of allergic rhinitis.
- Vitamin C is an antioxidant which protects cells from free radical damage and supports the body's immune function.
- Echinacea and Pelargonium possess immunostimulant properties which help support the immune system.
- Citrus bioflavonoids contain vitamin c which protects cells from free radical damage and supports the body's immune function.

- Vitamin D and Zinc contribute to the maintenance of immune function.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid

Trusil lemon flavour

Contains sugar: isomalt 4 g/sachet

Contains sweeteners: Acesulfame K: Sucralose 26 mg/sachet

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

Cartons containing 10 x 6g sachets

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

October 2021