

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

FLUGON capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredient	Per Capsule
<i>Echinacea Purpurea</i> (Echinacea) [leaf extract 4:1]	40 mg
<i>Sophora Japonica L.</i> (Quercetin) [flower & bud]	30 mg
<i>Pelargonium Sidoides</i> SPE60 (Pelargonium) [root extract]	25 mg
<i>Piper nigrum</i> (Piperine) [fruit extract 95 %]	2 mg
Vitamin C (as Ascorbic Acid)	100mg
Zinc (as Zinc Gluconate)	2,5 mg
Folic Acid	60 ug

Sugar free.

3 PHARMACEUTICAL FORM

Red and white capsules marked "FLUGON"

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

FLUGON capsules provide immune defence and help alleviate cough, sore throat and a blocked or runny nose.

4.2 Posology and method of administration

The recommended dose is as follows:

For daily immune system support:

Adults and children 12 years and older:

Take 2 capsules daily.

Children 6 – 12 years old:

Take 1 capsule daily.

At the first sign of a cold/flu:

Adults and children 12 years and older:

Take 2 capsules 4 times a day.

Children 6 – 12 years old:

Take 1 capsule 4 times a day.

If symptoms persist for longer than 5 days, consult a healthcare provider.

4.3 Contraindications

- Hypersensitivity to any of the active or inactive ingredients contained in FLUGON capsules.
- Children under the age of 6 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.

4.5 Interaction with other medicines and other forms of interaction

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

- Antidiabetic medicines: concomitant use of Quercetin with diabetes medicines may increase the risk of hypoglycaemia.
- Antihypertensive medicines: Quercetin can have additive blood pressure lowering effects and increase the risk of hypotension.
- Blood thinning medicines: Pelargonium contains coumarins which may potentiate bleeding.
- Cytochrome P450 substrates: Echinacea and Quercetin 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.
- Theophylline, Rifampicin, Phenytoin: Piperine increases levels of these medicines if taken together.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established. 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. 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

- Vitamin C is an antioxidant which protects cells from free radical damage and supports the body's immune function.

- Echinacea, Pelargonium and Piperine extract possess immunostimulant properties which help support the immune system.
- Quercetin is an antioxidant with anti-allergic effects.
- Zinc is an essential mineral which contributes to the maintenance of immune function.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium stearate
Microcrystalline cellulose
Sugar free

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

White plastic containers with 50 capsules

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

September 2020