PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

FLUGON COUGH SYRUP

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
The active ingredients are:

Ingredients	Per 5 ml
Pelargonium sidoides S70 (Pelargonium) [root extract]	28,6 mg
Hederea helicis folium (English Ivy) [leaf extract 4-8:1]	35 mg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Red to brown coloured syrup with a sweet fruity aroma

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

FLUGON COUGH SYRUP helps to loosens phlegm and thin mucus thereby easing a tight chest.

4.2 Posology and method of administration

The recommended dose is as follows:

Adults and children 12 years and older:
5 – 7,5 ml three times a day
Children 6 – 12 years: 2,5 – 5 ml twice daily
Children 1 – 5 years: 2,5 twice daily

Shake well before use.

4.3 Contraindications
- Hypersensitivity to any of the active or inactive ingredients contained in FLUGON COUGH SYRUP.

4.4 Special warnings and precautions for use
- Use in children under the age of 1 year is at the discretion of the healthcare professional.
- 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 medicine.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed on FLUGON COUGH SYRUP, however 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.

4.6 Fertility, pregnancy and lactation

FLUGON COUGH SYRUP 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.

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 help support the immune system.
- English Ivy possesses antioxidant, expectorant, secretolytic and antispasmodic properties.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Avicel, cherry flavour, glycerine, sodium carboxymethyl cellulose. Contains sugar: sorbitol 2,83 g/5ml
Preservatives: Potassium sorbate 0,036 % m/v; Sodium benzoate 0,047 % m/v

6.2 Incompatibilities
Unknown

6.3 Shelf life
2 years

6.4 Special precautions for storage
Store at or below 25 °C. Keep bottle tightly closed and protect from sunlight and moisture.
KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container
Bottles containing 200ml.

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 SAHPRA for its quality, safety or intended use.

9 DATE OF PUBLICATION OF PROFESSIONAL INFORMATION
September 2020