

PROFESSIONAL INFORMATION

SCHEDULING STATUS

S0

1 NAME OF THE MEDICINE

FLUGON PLUS

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	Per tablet
Herbal extract proprietary blend containing:	350 mg
<i>Zingiber officinale</i> (Ginger) [dried rhizome extract]	20 mg
<i>Echinacea angustifolia</i> (<i>Echinacea</i>) [plant extract]	10 mg
<i>Forsythia suspensa</i> (<i>Forsythia</i>) [fruit extract]	10 mg
<i>Isatis tinctoria</i> (<i>Isatis</i>) [root extract]	10 mg
<i>Lonicerae japonica</i> (<i>Honeysuckle</i>) [flower extract]	10 mg
<i>Schizonepeta multifida</i> (<i>Schizonepeta</i>) [plant extract]	10 mg
<i>Vitex trifolia</i> (<i>Chinese vitex</i>) [fruit extract]	10 mg
Vitamin C (as ascorbic acid)	1000 mg
Potassium (from potassium bicarbonate)	75mg
Lysine (from L-lysine hydrochloride)	40 mg
Magnesium (from magnesium sulphate)	40 mg
Glutamine (from L-glutamine)	10 mg
Zinc (from zinc sulphate)	8 mg
Manganese (from manganese gluconate)	3 mg
Vitamin B2 (from riboflavin sodium phosphate)	2,8 mg
Vitamin A (from vitamin A palmitate)	2000 IU
Vitamin E (as dl-alpha tocopheryl acetate)	30 IU
Selenium (from selenium glycinate)	15 ug

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Round light-yellow effervescent tablets with the smell of oranges.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

FLUGON PLUS is a health supplement containing herbal extracts, vitamins and minerals which help support your immune system.

4.2 Posology and method of administration

Adults and children 12 years and older:

Take one tablet dissolved in water daily.

Wait for the effervescence to subside before drinking.

Do not chew the tablets or swallow them whole.

4.3 Contraindications

- Hypersensitivity to any of the active or inactive ingredients.
- Patients allergic to aspirin.
- Children under the age of 12 years.

4.4 Special warnings and precautions for use

- Use with caution in patients with a history of kidney stones and in patients with kidney disease.
- Use with caution in patients on a sodium-restricted diet as this medicine contains a large amount of sodium.

- Echinacea has immunostimulant properties and may exacerbate autoimmune conditions.
- Schizonepeta may exacerbate liver dysfunction in patients with liver disease.
- Chinese vitex may have hormonal effects and may affect oestrogen levels. Caution is advised in patients with hormone sensitive conditions.
- Use with caution in patients with cancer, or those receiving chemotherapy.
- Herbal extracts may potentiate bleeding - use with caution in patients on anticoagulants or antiplatelets.
- Contains sorbitol which may affect glycaemic control in 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 were performed on FLUGON PLUS however the following interactions are noted in the monographs of the active ingredients:

- Patients on chemotherapy should only take FLUGON PLUS under the supervision of their oncologist.
- Antidiabetic medicines as ginger and echinacea may lower blood sugar levels.
- Concomitant use with anticoagulant or antiplatelet medicines may increase the risk of bleeding.
- Immunosuppressants as Echinacea may interfere with their action.
- Oral contraceptives and hormone replacement therapy as Chinese vitex may have hormone modulating effects.
- Anti-epileptic medicines as glutamine may interfere with their efficacy.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established.

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

Skin rash, hives, skin redness, abdominal cramps, abdominal pain, nausea, vomiting, diarrhoea, dry mouth, heartburn and hematuria. Supplemental Vitamin C over 250 mg per day has been associated with a higher risk of kidney stones.

4.9 Overdose

In the event of an overdose, nausea, vomiting, diarrhoea, abdominal pain, fatigue, headache and confusion may occur. Treatment is symptomatic and supportive.

When used in excessive amounts, Schizonepeta may cause hepatotoxicity.

Prolonged use of high doses of vitamin C (2g per day) may cause renal calculi.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Discipline specific traditional claims D33.7 Multiple substance formulation

5.2 PHARMACOLOGICAL ACTION

Vitamin C

- is an antioxidant which protects cells from free radical damage and contributes to normal immune function.
- 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.

Manganese, Vitamin E, Selenium and Zinc are antioxidants which contribute to the protection of cells from oxidative stress and to normal function of the immune system.

Vitamin A contributes to the normal function of the immune system.

Herbal extracts possess immunostimulant properties which help support the immune system.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid anhydrous, isopropyl alcohol (evaporates during manufacture - not present in final product), maltodextrin, orange flavour, sodium bicarbonate, simethicone, sodium benzoate, sodium carbonate.

Contains sugar: sorbitol 300 mg/tablet

Contains sweeteners: sucralose 20 mg/tablet and acesulfame potassium 20 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 bottle tightly closed to protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

Tubes containing 20 tablets packed in a cardboard carton.

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 2021