

# PROFESSIONAL INFORMATION

## SCHEDULING STATUS

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## 1 NAME OF THE MEDICINE

FLUGON FIZZY (ADULT) (effervescent tablets)

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredient	Per tablet
Methylsulfonyl methane (MSM)	200 mg
<i>Echinacea Purpurea</i> (Echinacea) [leaf extract 4:1]	80 mg
<i>Pelargonium Sidooides</i> SPE60 (Pelargonium) [root extract]	60 mg
<i>Sophora Japonica</i> L. (Quercetin) [flower & bud]	60 mg
Citrus aurantium L. (Citrus Bioflavonoids) [fruit extract 13 %]	40 mg
<i>Piper nigrum</i> (Piperine) [fruit extract 95 %]	2 mg
Vitamin C (as ascorbic acid)	194 mg
Vitamin A (as Beta carotene 10%)	10 mg
Zinc Gluconate 6,36 mg Providing Zinc (elemental)	0,91 mg
Selenium glycinate 2% 1 mg Providing Selenium (elemental)	20 µg
Cholecalciferol (Vitamin D3)	150 IU (3,75 µg)

For full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Yellow, speckled, round, flat tablet with characteristic orange flavour

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indication

FLUGON FIZZY supports the immune system and helps alleviate cough, sore throat and a blocked or runny nose.

### 4.2 Posology and method of administration

The recommended dose is as follows:

#### At first signs of colds and flu:

Adults and children over 12 years:  
One tablet dissolved in water three times daily for 5 days.

#### For daily immune system support:

One tablet dissolved in water daily.

Wait for effervescence to subside before drinking.

### 4.3 Contraindications

- Hypersensitivity to any of the active or inactive ingredients contained in FLUGON FIZZY.
- Patients allergic to sulphur should not take FLUGON FIZZY.
- 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*.

## 4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed on FLUGON FIZZY. 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 Medicine: Discipline Specific Traditional Claims - D33.7 Combination Product

## 5.2 PHARMACOLOGICAL ACTION

- **Methylsulfonyl methane has anti-allergy properties**
- Vitamin C is an antioxidant which protects cells from free radical damage and contributes to normal immune function. It 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.
- Echinacea, Pelargonium and Piperine extract possess immunostimulant properties which help support the immune system.
- Quercetin is an antioxidant with anti-allergic effects.
- Piperine extract is an antioxidant and supports the immune system.
- Citrus bioflavonoids contain vitamin c which protects cells from free radical damage and supports the body's immune function.
- Zinc is an antioxidant which contributes to the protection of cells from oxidative stress, maintenance of immune function, cognitive function, normal vision, and normal skin, hair and bones. It contributes to DNA synthesis, acid-base metabolism, normal fertility and reproduction, normal testosterone levels, macronutrient metabolism, connective tissue formation, plays a role in the process of cell division and helps the body metabolize carbohydrates, fats and proteins.
- Selenium is an antioxidant which contributes to the protection of cells from oxidative stress, maintenance of immune function, normal hair and nails, contributes to normal spermatogenesis and normal thyroid function.
- Vitamin D contributes to normal cell division, normal immune function, helps in the absorption and use of calcium and phosphorus, contributes to normal blood calcium levels, development and maintenance of strong bones and teeth, normal muscle function and has a role in the process of cell division. Calcium intake, when combined with sufficient vitamin D, a healthy diet and exercise, may reduce the risk of developing osteoporosis.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Citric acid, magnesium stearate, polyethylene glycol, sodium bicarbonate, orange flavouring and silicon dioxide.

Contains sugar: isomalt 407 mg/tablet

Contains sweeteners: Sucralose 25 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 tube tightly closed and protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

### 6.5 Nature and contents of container

Tubes containing 12 tablets.

### 6.6 Special precautions for disposal and other handling

No special requirements

## 7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd

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## 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

July 2021