

## PROFESSIONAL INFORMATION

### SCHEDULING STATUS

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### 1 NAME OF THE MEDICINE

FLUGON VAPOBALM

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

FLUGON VAPOBALM contains 5 % Menthol, 5 % tea tree oil and 1,5 % Eucalyptus oil.

For full list of excipients, see section 6.1

### 3 PHARMACEUTICAL FORM

White ointment with a menthol smell.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indication

FLUGON VAPOBALM helps alleviate nasal congestion associated with colds and flu.

#### 4.2 Posology and method of administration

##### For external use only

Adults and children over 2 years:

RUB ON METHOD - Apply to the chest, neck and back. Massage for 3 - 5 minutes. Clothing should be loose to allow vapours to be inhaled easily.

INHALATION METHOD - Dissolve 2,5 ml into 500 ml hot water (not boiling). Inhale the aromatic vapours for 10 - 15 minutes. Dispose of the mixture once done.

Do not use more than the recommended dose. If symptoms persist for longer than 5 days, consult your healthcare provider.

#### 4.3 Contraindications

- Hypersensitivity to any of the active or inactive ingredients contained in FLUGON VAPOBALM.
- Children under the age of 2 years.

#### 4.4 Special warnings and precautions for use

- Avoid contact with eyes
- Do not swallow or place in nostrils
- Do not reheat the mixture or heat whilst inhaling.

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

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

Amphetamines: inhalation of eucalyptol may reduce the levels of amphetamines in the blood.

Pentobarbital: inhalation of eucalyptol may reduce the level of pentobarbital that reaches the brain.

#### 4.6 Fertility, pregnancy and lactation

FLUGON VAPOBALM 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 with eucalyptus oil include contact dermatitis, skin irritation, local redness, stinging and irritation of the eyes and nose.

#### 4.9 Overdose

Symptoms of inhalational overdose include stinging/itchy, watery eyes and nose and cough. Treatment is symptomatic and supportive.

Eucalyptus oil and tea tree oil are toxic if ingested. In case of accidental ingestion, seek immediate medical attention.

### 5 PHARMACOLOGICAL PROPERTIES

#### 5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Discipline specific traditional claims  
D33.7 Combination product

#### 5.2 PHARMACOLOGICAL ACTION

Eucalyptus oil is well absorbed through steam inhalation to help relieve nasal congestion.

### 6 PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Emulsifying wax, microwax, petroleum jelly white.

#### 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 tubs containing 30 g

#### 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

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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

September 2020