

## PROFESSIONAL INFORMATION FOR HUMAN MEDICINES

### SCHEDULING STATUS

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### 1 NAME OF THE MEDICINE

Vicks Inhaler

41,54 % Levomenthol; 41,54 % Racemic Camphor

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1,0 g medication for nasal use contains:

Levomenthol 415,4 mg; Racemic Camphor 415,4 mg

*For a full list of excipients, see section 6.1*

### 3 PHARMACEUTICAL FORM

Nasal Inhaler

A cellulose wick impregnated with a mobile, slightly oily liquid medication, slightly yellow in colour encased in a plastic holder.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

The relief of nasal congestion associated with allergic and infectious upper respiratory tract disorders.

#### 4.2 Posology and method of administration

##### *Posology*

Adults and children over 6 years: It can be used as frequently as needed.

##### *Paediatric population*

Do not used in children under 6 years.

##### *Method of administration*

Vicks inhaler is used by inserting the inhaler into one nostril, while holding the other nostril closed and inhaling

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deeply.

Use only as intended. For external use only (see section 6.6).

If no significant improvement in symptoms has occurred after 7 days, the patient is advised to consult a doctor because a more serious illness may be present.

#### 4.3 Contraindications

Hypersensitivity to menthol, camphor or to any of the excipients listed in section 6.1.

Asthma and other respiratory hypersensitivities.

#### 4.4 Special warnings and precautions for use

If there is no improvement or if there is aggravation of the disorder consult your doctor.

Avoid contact with the eyes.

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

None.

#### 4.6 Fertility, pregnancy and lactation

There is no evidence to indicate that this product should not be used during pregnancy and lactation.

#### 4.7 Effects on ability to drive and use machines

None.

#### 4.8 Undesirable effects

In general, no serious or severe side effects are expected with this product.

Consult a doctor if symptoms persist.

Medra System Organ Class	Frequency	Side Effects
Immune system disorders	Very rare	Hypersensitivity reactions including contact dermatitis
Respiratory, thoracic and mediastinal disorders	Very rare	Nasal discomfort (e.g. temporary burning, stinging, sneezing, or increased nasal discharge)

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#### *Reporting of suspected adverse reactions*

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested ~~asked~~ to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

#### **4.9 Overdose**

No clinically significant cases of overdose have been reported.

Treatment is symptomatic and supportive.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Class of medicine: A.10.2.1 Inhalants

ATC code: R01AX10

Vicks inhaler contains special aromatic ingredients, having decongestant and cooling effects on the nasal mucosa in the upper respiratory tract. In this way, they immediately produce a subjective feeling of better nasal breathing and soothing of the nasal mucosa.

#### **5.2 Pharmacokinetic properties**

Pharmacokinetic information is not required for therapeutic use given the route of administration and the amounts ingested (~0,5 mg).

The product exerts its action locally; little or no absorption is expected to occur.

#### **5.3 Preclinical safety data**

Toxicology information is not required for therapeutic use given the route of administration and the amounts ingested (~0,5 mg).

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Siberian Pine Needle Oil

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Methyl Salicylate

## **6.2 Incompatibilities**

None.

## **6.3 Shelf life**

36 months

## **6.4 Special precautions for storage**

Store in a cool, dry place at or below 25 °C.

## **6.5 Nature and contents of container**

Vicks Inhaler comprises a cellulose acetate wick impregnated with 1,0 ml of liquid medication. The impregnated wick is enclosed within a plug and nose piece and the unit is sealed with screw-thread closure. All three packaging components are made of white Polypropylene.

## **6.6 Special precautions for disposal <and other handling>**

Use only as intended. For external use only.

## **7 HOLDER OF CERTIFICATE OF REGISTRATION**

P&G South African Trading (Pty) Ltd.

Alice Lane Towers, 15 Alice Lane

Sandton

2196

Johannesburg

South Africa

## **8 REGISTRATION NUMBER(S)**

G1258/Act 101/1965

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**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

September 2009

**10 DATE OF REVISION OF THE TEXT**

18 August 2025