

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Vicks Vaporub

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Name of the active substances:

Levomenthol 2.75% W/W

Camphor 5.00% W/W

Eucalyptus Oil 1.50% W/W

Turpentine Oil 5.00% W/W

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

An ointment which is rubbed on chest or added to hot water and the aromatics are inhaled.

## 4 CLINICAL PARTICULARS

### 4.1. Therapeutic indications

For the symptomatic relief of nasal catarrh and congestion, sore throat, also cough due to colds.

### 4.2 Posology and method of administration

Adults:

Rub liberally on the chest, throat and back. Rub in well over the whole area and leave nightclothes loose to allow vapours to be inhaled easily.

or

Melt two teaspoons in a bowl of very hot (not boiling) water and inhale the vapours for 10-15 minutes.

Children (infants and babies over 2 years):

Apply a small amount on the chest and back. Rub gently and leave clothes loose for easy inhalation.

#### **4.3 Contraindications**

- Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.
- Do not administer to children < 2 years.
- Do not use as an inhalation for children < 12 years.

#### **4.4 Special warnings and precautions for use**

The following patient groups should use with caution or consult a doctor or pharmacist before use:

- History of airway disease or pronounced hypersensitivity of the airways / asthma.

##### **Topical warnings:**

- Do not apply to broken skin, wounds, or mucous membranes.
- Do not swallow or apply directly onto the nostrils, eyes, mouth, or face. For external use only.
- Do not bandage tightly. Do not use with heat wrap or any kind of heat.

##### **Inhalation warnings:**

- Do not use boiling water to prepare inhalations.
- Do not heat or re-heat the mixture in a microwave.

**Instruct patients not to smoke or go near naked flames - risk of severe burns.** Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

None known

#### **4.6 Pregnancy and lactation**

As with all medicines in pregnancy, care should be taken and as a precaution this product should not be used without medical advice during pregnancy. Vaporub should not be used on the mother's chest during lactation, due to the theoretical risk of apnoea reflex in the infant whilst feeding in close proximity to the site of application.

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

This product does not interfere with the ability to drive vehicles or use machinery

#### **4.8 Undesirable effects**

General disorders and administration site conditions:

- Redness, irritation of the skin, irritation of the eyes (by inhalation), allergic dermatitis.
- Irritations or allergic reactions are usually mild and occur rarely.
- Frequency not known (cannot be estimated from the available data): Burns at application site.

Systemic effects: Due to the recommended route of administration; systemic exposure is very low and undesirable effects due to systemic exposure have not been observed.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard), or search for MHRA Yellow card in Google Play or Apple App store.

#### **4.9 Overdose**

Over dosage may result in skin irritation.

Misuse:

Swallowing of the ointment might cause gastrointestinal symptoms like vomiting and diarrhoea. Treatment is symptomatic.

After significant accidental consumption, acute poisoning was observed after significant accidental consumption, with nausea, vomiting, abdominal pain, and headache, vertigo, feeling hot / flushing, convulsions, respiratory depression and coma.

In case of accidental ingestion seek medical assistance.

Patients with severe gastrointestinal or neurological symptoms of poisoning should be observed and treated symptomatically. Do not induce vomiting.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Menthol, camphor, turpentine oil and eucalyptus oil act locally in the respiratory tract.

### **5.2. Pharmacokinetic properties**

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

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

Not applicable.

## **6 PHARMACEUTICAL PARTICULARS**

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

Thymol  
Cedarwood oil  
White soft paraffin

### **6.2. Incompatibilities**

None.

### **6.3 Shelf life**

Jar: 48 months  
Easy applicator: 24 months

### **6.4. Special precautions for storage**

Do not store above 25°C.

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

Vaporub ointment is packed into:

- Jar: 40g, 50g, 90g and 100g opaque, blue, polypropylene jars, closed with a green polypropylene thread screw cap and containing a 2mm thick PET/LDPE/EPE/LDPE/PET cap liner. The jar is placed into a carton.
- Easy applicator: 35g container assembly made of blue-colour polypropylene (PP) for body, base and screw parts; High Density Polyethylene (HDPE) for piston; nitrile butadiene rubber (NBR) for gasket. The applicator is placed into a carton.

### **6.6. Instructions for use, handling and disposal**

None.

**7      MARKETING AUTHORISATION HOLDER**

Procter & Gamble (Health & Beauty Care) Limited  
The Heights  
Brooklands  
Weybridge  
Surrey  
KT13 OXP

**8.     MARKETING AUTHORISATION NUMBER**

PL 00129/0130

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

15<sup>th</sup> March 1999

**10    DATE OF REVISION OF THE TEXT**

28/03/2024