Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vicks Vaporub Inhalation Vapour, Ointment Levomenthol 2.75% w/wCamphor 5.00% w/wEucalyptus Oil 1.50% w/w Turpentine Oil 5.00% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Name of the active substances:	Quantity	Unit
Levomenthol	2.75	% w/w
Camphor	5.00	% w/w
Eucalyptus oil	1.50	% w/w
Turpentine oil	5.00	% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation vapour, ointment
A soft, white or yellow unctuous ointment with a characteristic odour.

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

Topical
Adults and children over 2 years
Rub the indicated amount onto the areas indicated (e.g. chest, back) and repeat up to 2-4 times a day as needed. Wear loose clothing to facilitate the inhalation of the vapours.

Inhalation
Adults and children over 6 years:

Place 1 – 2 x 5ml Spoonfuls as indicated into a bowl of hot (not boiling) water. Inhale the vapours for up to 10 – 15 minutes per time. Do not heat in the microwave or reheat this mixture. Children should always be supervised.

4.3 Contraindications

Hypersensitivity to any of the ingredients.
Do not administer to children < 2 years.
Do not use as an inhalation for children < 6 years.

4.4 Special warnings and precautions for use

The following patient groups should use with caution or consult a doctor before use;
History of airway disease or pronounced hypersensitivity of the airways / asthma
Keep out of reach and sight of children.
If symptoms persist, consult your doctor

Topical:
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.

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

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, 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

Local effects:
Redness, irritation of the skin, irritation of the eyes (by inhalation), allergic dermatitis. Irritations or allergic reactions are usually mild and occur rarely.

General disorders and administration site conditions:
Burns at application site – frequency not known.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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.

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

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 known.

6.3 Shelf life

48 months.

6.4 Special precautions for storage

Do not store above 25^{o}C.

6.5 Nature and contents of container

The product is contained in a blue, polypropylene, injection/blow moulded jar with a green polypropylene, wadless cap containing a 2 mm thick PET / LDPE / EPE / LDPE / PET cap liner. The jar is enclosed in a printed cardboard carton. Pack sizes of 40g, 50g, 90g and 100g are available.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

WICK Pharma - Zweigniederlassung der Procter & Gamble GmbH
Sulzbacher Str. 40
65823 Schwalbach am Taunus
Germany

8 MARKETING AUTHORISATION NUMBER

PA2294/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 June 2000

Date of last renewal: 23 June 2010

10 DATE OF REVISION OF THE TEXT

January 2019