SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Vicks Inhaler

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS

	mg/inhaler	Specification
Menthol	125.00	EP
Camphor	50.00	EP
Siberian Pine Needle Oil	10.00	FP

3 PHARMACEUTICAL FORM

Nasal stick; for nasal use.

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

Adults and children over 6 years: Vicks Inhaler is used by inserting the inhaler into each nostril, holding the other nostril closed and inhaling deeply.

It can be used as frequently as needed.

Children under 6 years: Not recommended.

4.3 Contraindications

Use in patients hypersensitive to any of the ingredients.

4.4 Special warnings and precautions for use

If symptoms persist consult your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

No effects during pregnancy are anticipated, since systematic exposure to Menthol, Camphor and Siberian Pine Needle Oil is negligible. Vicks Inhaler can be used during pregnancy.

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.

Very rarely cases of nasal discomfort have been reported.

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.

4.9 Overdose

Symptoms: No clinically significant cases of overdose have been reported. **Management of an overdose:** None

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Menthol, Camphor and Siberian Pine Needle 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

Methyl salicylate

6.2 Incompatibilities

None.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

A cellulose wick soaked in medication enclosed in a plastic holder with a plastic wick.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Procter & Gamble (Health & Beauty Care) Limited

The Heights

Brooklands

Weybridge

Surrey

KT13 0XP

UK

8 MARKETING AUTHORISATION NUMBER

PL 00129/5009R

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14/06/2004

10 DATE OF REVISION OF THE TEXT

25/10/2016