

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Vicks Inhaler Nasal StickMenthol 125mgCamphor 50mgSiberian Pine Needle Oil 10mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

ACTIVE INGREDIENTS

	<u>mg/inhaler</u>
Menthol	125.00
Camphor	50.00
Siberian Pine Needle Oil	10.00

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Nasal Stick

The nasal stick contains a cellulose wick soaked in 0.5ml of product.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the relief of symptoms of nasal congestion such as are 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 there is no improvement or aggravation of the disorder consult the doctor.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

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. 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 HPRC 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

No clinically significant cases of overdose have been reported.

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

Not applicable.

6.3 Shelf life

3 years.

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 (0.5 ml) enclosed in a polypropylene plastic holder, with a polypropylene cap.

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

PA2294/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th November 1988

Date of last renewal: 18th November 2008

10 DATE OF REVISION OF THE TEXT

January 2019