Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Karvol Inhalation Vapour, Liquid

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances

Chlorbutol	0.5 % w/w
Levomenthol	7.9 % w/w
Pine Oil Sylvestris	2.0 % w/w
Terpineol	14.8 % w/w
Thymol	0.7 % w/w
Pumilio Pine Oil	22.9 % w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation vapour, liquid
Golden yellow, oily liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of nasal congestion associated with colds in the head.

4.2 Posology and method of administration

For older children and adults:

For relief throughout the night: Sprinkle 6 drops onto bedding or handkerchief nearby but avoiding direct skin contact.

Daytime: Sprinkle 6 drops onto a tissue or into a pint of hot water and inhale the vapours freely.

For young children:

For daytime use and relief throughout the night: sprinkle 6 drops onto a handkerchief tied down securely in the vicinity, but out of reach of the child.

Elderly:

There is no need to modify the administration of this preparation for use by the elderly.

Children under 3 months:

Not recommended for children under 3 months of age.

4.3 Contraindications

Children under 3 months of age.

4.4 Special warnings and precautions for use

Avoid contact with the eyes and prolonged contact with the skin.
If symptoms persist consult your doctor.
Keep all medicines out of the reach of children.
For inhalation only.
Do not put drops directly in mouth or nose.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions known.

4.6 Pregnancy and lactation

The safety in pregnancy and lactation has not been established, but is not expected to constitute a hazard.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

No adverse effects known.

4.9 Overdose

Symptoms of massive overdose by ingestion include nausea, vomiting, colic, headache, dizziness, a feeling of warmth, delirium, muscle twitching, epileptiform convulsions, depressed respiration, CNS depression and coma. Initial treatment consists of emptying the stomach by lavage and aspiration. Administer a saline laxative such as sodium sulphate and activated charcoal by mouth.

Convulsions may be controlled with diazepam or thiopentone sodium.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlorbutol, levomenthol, pine oil, terpineol and thymol are volatile substances and are thought to produce an irritant effect on the respiratory tract, possibly via a nasal pulmonary arch.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol monooleate
Cinnamon oil
Polysorbate 80
Macrogol 400
Triacetin

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Do not store above 25^{o}C. Store in an upright position. Replace cap tightly after use.

6.5 Nature and contents of container

The liquid is contained in an amber glass bottle fitted with a combined all-in-one polyethylene/polypropylene dropper and a tamper evident child resistant polypropylene cap. The bottle is presented in a cardboard carton. Pack size 12 ml.

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

Whilst applying the drops ensure that the dropper bottle is held vertically.

7 MARKETING AUTHORISATION HOLDER

Crookes Healthcare Limited
1 Thane Road West
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8 MARKETING AUTHORISATION NUMBER

PA 43/4/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 August 1999

Date of last renewal: 23 August 2004

10 DATE OF REVISION OF THE TEXT

July 2006