Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Karvol Decongestant Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains

Chlorbutanol Hemihydrate	2.25mg
Levomenthol	35.55mg
Pine Oil Sylvestris blend	9mg
Terpineol	66.6mg
Thymol	3.15mg
Pumilio Pine Oil blend	103.05mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation vapour, Capsule.
Light brown, flask-shaped capsule containing a slightly yellow oil with a characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of nasal congestion and colds in the head.

4.2 Posology and method of administration

Babies over three months and young children:
Snip top off capsule carefully and squeeze contents onto a handkerchief tied securely near to, but out of reach of the child

Older children and adults:
Snip tip off capsule carefully, pointing top downwards and away from the face. Carefully sprinkle the contents onto bedding or material, avoiding the possibility of skin contact. Alternatively, add to a pint of hot water and inhale vapour freely.

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.
Do not take internally

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions known.

4.6 Fertility, pregnancy and lactation

The safety of Karvol in pregnancy and lactation has not been established, but is not expected to constitute a hazard. Seek doctor or pharmacists advice when pregnant.

If using hot water to vaporise the product the water should not be boiling. Care should be taken with hot water to avoid spillage and scalds. Children should not be left alone with hot water.

4.7 Effects on ability to drive and use machines

No clinically significant interactions known.

4.8 Undesirable effects

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

4.9 Overdose

Symptoms of overdose 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 arc.

5.2 Pharmacokinetic properties

Not applicable

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cinnamon Oil
Macrogol – 20 Stearate
Polysorbate 80
Macrogol 400
Triacetin

Capsule Shell
Gelatin
Glycerol
Purified water

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

AL/PVC/PVDC blister containing 10, 12, 24 Capsules. Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 0979/061/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation : 1st April 1983

Date of last renewal : 1st April 2008

10 DATE OF REVISION OF THE TEXT

April 2010