SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Menthol and Eucalyptus Inhalation BP 1980

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Menthol BP	2.0% w/v
Eucalyptus Oil BP	10.0% v/v

Excipients with known effects

Benzalkonium chloride	0.025% w/v

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For relief of the symptoms of coughs, colds and blocked noses

4.2 Posology and method of administration

Inhaled via the mouth and nasal passages.

Adults, children over 3 months of age and the elderly:
Add one 5ml spoonful to a pint of hot, but not boiling water.
The dose may be repeated after 4 hours if required.

4.3 Contraindications

Not suitable for children under 3 months.

Contra-indicated in patients with hypersensitivity to menthol, eucalyptus or any of the other ingredients

4.4 Special warnings and precautions for use

Not suitable for children under 3 months.

For external use only

Keep all medicines away from children.

This medicine contains 1.25mg benzalkonium chloride in each 5ml dose, which is equivalent to 0.025% w/v. Benzalkonium chloride may cause wheezing and breathing difficulties (bronchospasm), especially if you have asthma.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Fertility, pregnancy and lactation

Use of this product in the above conditions is not considered likely to cause any harmful effects.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

Menthol may give rise to hypersensitivity reactions including contact dermatitis. There have been reports of apnoea and instant collapse in infants following the local application of menthol to their nostrils.

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 of poisoning with swallowed menthol and eucalyptus inhalation include epigastric burning, severe abdominal pain, central nervous system depression, pulmonary damage, nausea and vomiting, drowsiness, dizziness and muscular weakness, ataxia, miosis, coma and a feeling of suffocation. Cyanosis, delirium and convulsions may occur. Deaths have been recorded from doses as low as 3.5ml of eucalyptus oil (equivalent to 35m1 of the inhalation). The fatal dose of menthol in man has been estimated to be about 2g (equivalent to 100ml of the inhalation).

Treatment should consist of emptying the stomach by gastric lavage and aspiration. Administer a saline laxative by mouth, such as sodium sulphate, 30g in 250ml of water, or a dilute solution of sodium phosphate. Convulsions may be controlled by the use of parenteral anticonvulsant agents. The latter treatment would require hospitalisation.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Eucalyptus oil has been used as an inhalation, often in combination with other volatile substances. It has also been taken by mouth for catarrh and applied externally as a rubefacient.
Menthol is used to relieve symptoms of bronchitis, sinusitis and similar conditions.

5.2 Pharmacokinetic properties

No information available.

5.3 Preclinical safety data

None

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Magnesium carbonate light BP, benzalkonium chloride BP and purified water BP.

6.2 Incompatibilities

None known

6.3 Shelf life

36 months unopened.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

100ml:	Glass bottle with white 28mm Child-Resistant cap with tamper evident band and EPE/Saranex Liner.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

L. C. M. Ltd.

Linthwaite Laboratories

Huddersfield

HD7 5QH

8 MARKETING AUTHORISATION NUMBER(S)

PL 12965/0027

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/09/1993 / 26/09/2002

10 DATE OF REVISION OF THE TEXT

07/09/2020