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

For excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Inhalation solution.

4 CLINICAL PARTICULARS

4.1. Therapeutic Indications

For the relief of the symptoms of coughs, colds and nasal congestion.

4.2 Posology and method of administration

Posology

Adults, elderly and children over three months of age

Add one 5ml spoonful to a pint of hot but not boiling water.

Inhale the vapour.

The dose may be repeated every four hours if required.

Children under three months of age

Not suitable.

Method of administration

Inhalation

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Not suitable for children under 3 months of age.

4.4 Special warnings and precautions for use

Shake the bottle well before use. Use within 6 months of opening.

Not to be taken by mouth.

If symptoms persist consult your doctor.

Keep all medicines out of the sight and reach of children.

4.5. Interactions with other Medicinal Products and other Forms of Interaction

No significant interactions have been reported.

4.6 Fertility, pregnancy and lactation

No significant effects have been reported. As with all medicines, the use of the product during pregnancy or lactation should only be undertaken when the benefits are considered to outweigh the risks.

4.7. Effects on Ability to Drive and Use Machines

No significant effects would be expected under therapeutic use.

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 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

Prolonged inhalation of menthol (from mentholated cigarettes) has been reported to produce insomnia, unsteady gait, thick speech, tremor of the hands, mental confusion, depression, vomiting, cramp in the legs and bradycardia. The acute inhalation of 200mg menthol has been reported to produce ataxia, confusion, euphoria, nystagmus and diplopia. Other symptoms of poisoning with menthol include severe abdominal pain, nausea, vertigo, drowsiness and coma. The fatal dose of menthol in man has been estimated to be about 2g (equivalent to 100ml of Menthol & Eucalyptus Inhalation B.P. 1980).

Symptoms of ingestion of menthol and eucalyptus oil include epigastric burning, severe abdominal pain, nausea and vomiting, drowsiness, dizziness, muscular weakness and CNS depression including coma. Cyanosis, ataxia, miosis, pulmonary damage, a feeling of suffocation, delirium and convulsions may occur. Deaths have been recorded from doses as low as 3.5ml of eucalyptus oil (equivalent to 35ml of Menthol & Eucalyptus Inhalation B.P. 1980).

Treatment

Empty 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 parenteral anticonvulsant agents. The latter treatment would require hospitalisation.

5.1. Pharmacodynamic Properties

Inhalation of the volatile ingredients, menthol and eucalyptus oil, encourages inspiration of warm moist air providing relief from coughing and nasal obstruction. Menthol also produces an analgesic effect and a sensation of coldness which may give a sensation of increased air flow.

5.2. Pharmacokinetic Properties

After absorption, menthol is excreted in the urine and bile as glucuronide. No information has been found available on eucalyptus oil.

5.3. Preclinical Safety Data

No relevant data.

6 PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Light Magnesium Carbonate
Potable water

6.2. Incompatibilities

No significant incompatibilities have been reported.

6.3. Shelf Life

36 months.
6 months in use.

6.4. Special Precautions for Storage

Do not store above 25°C.

6.5. Nature and Contents of Container

Dispensing packs

500ml amber glass bottle with white plastic screw cap with an aluminium faced EPE liner.

Patient packs or OTC pack as appropriate

100ml amber glass bottle with white Jay cap closure.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None stated

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

PL 18374/0022

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

9th March 2005

10 DATE OF REVISION OF THE TEXT

15/12/2017