SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<TRADE NAME> <STRENGTH> Essential Oil

<REGARDING THE APPROVAL>

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Eucalyptus oil BP <STRENGTH>

Excipient with known effect:

<REGARDING THE APPROVAL>

For the full list of excipients, see section 6.1.

1. PHARMACEUTICAL FORM

Essential Oil

<REGARDING THE APPROVAL>

1. CLINICAL PARTICULARS
   1. Therapeutic indications

For the symptomatic relief of catarrh and coughs.

For relief of the symptoms of minor muscular sprains and cramps..

* 1. Posology and method of administration

1. (a) By inhalation from drops of oil spilled onto a handkerchief which is then sniffed.

(b) By inhalation of vapour from drops of oil spilled into a bowl of hot water (50oC) ‘steam inhalation’ and the humid vapour inhaled.

2. As a rubefacient during massage of sprains and cramps where massage is an appropriate treatment.

Recommended Dose and Dosage Schedule

Adults, the elderly and children over 1 year:

1. (a) Sprinkle a few drops on to a handkerchief and inhale as required.

(b) A few drops into warm/hot water (50°C) and inhale the humid vapour, as required.

2. A few drops on the hand to lubricate the massage of appropriate areas as required.

* 1. Contraindications

Sensitivity to Eucalyptus Oil.

Not recommended for infants under 1 year.

* 1. Special warnings and precautions for use

Keep all medicines out of the reach and sight of children. Not to be take orally.

If symptoms persist consult your doctor.

* 1. Interaction with other medicinal products and other forms of interaction

None known.

* 1. Fertility, pregnancy and lactation

No evidence can be found as to the safety of the product in pregnancy or lactation. The use of all drugs should be avoided during the first trimester.

* 1. Effects on ability to drive and use machines

At the dosage indicated, no evidence can be found that the product affects the ability to drive or to use machinery.

* 1. Undesirable effects

When used as a rubefacient it may induce skin sensitisation and eczema.

No adverse effects of inhalation are reported but in sensitised individuals the precipitation of hay fever or asthma are potential unwanted effects.

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 Health Product Vigilance Center; HPVC

* 1. Overdose

Symptoms: poisoning with eucalyptus oil may cause epigastric burning, nausea and vomiting, dizziness, muscular weakness, miosis, tachycardia, a feeling of suffocation, cyanosis, ataxia, pulmonary damage, delirium, convulsions and CNS depression, including coma. Deaths have been recorded from doses as low as 3.5ml.

Emergency procedures: after ingestion the stomach should be emptied by aspiration and lavage. Demulcent drinks may be given. Large volumes of fluid should be given provided renal function is adequate. Effects of excessive inhalation should be treated by removal to fresh air.

1. PHARMACOLOGICAL PROPERTIES
   1. Pharmacodynamic properties

When the vapour is inhaled eucalyptus oil acts to ventilate the bronchial passages and relieve bronchitis and associated conditions. It is also a rubefacient.

* 1. Pharmacokinetic properties

After ingestion excretion takes place via the lungs, skin and kidneys..

* 1. Preclinical safety data

None.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<REGARDING THE APPROVAL>

* 1. Incompatibilities

None known.

* 1. Shelf life

<REGARDING THE APPROVAL>

* 1. Special precautions for storage

<REGARDING THE APPROVAL>

* 1. Nature and contents of container

<REGARDING THE APPROVAL>

* 1. Special precautions for disposal

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION HOLDER

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION NUMBER(S)

<REGARDING THE APPROVAL>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<REGARDING THE APPROVAL>

1. DATE OF REVISION OF THE TEXT1

<REGARDING THE APPROVAL>