

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **1 NAME OF THE MEDICINAL PRODUCT**

Eucalyptus Oil BP

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Eucalyptus Oil BP 100% V/V

## **3 PHARMACEUTICAL FORM**

Essential Oil

### **4.1 Therapeutic indications**

For the symptomatic relief of catarrh and coughs.  
For relief of the symptoms of minor muscular sprains and cramps.

### **4.2 Posology and method of administration**

- 1a. 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 (50°C) '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.

### **4.3 Contraindications**

Sensitivity to Eucalyptus Oil.  
Not recommended for infants under 1 year.

### **4.4 Special warnings and precautions for use**

Keep all medicines out of sight and reach of children.  
Not to be taken orally.  
If symptoms persist consult your doctor.

### **4.5 Interaction with other medicinal products and other forms of interaction**

None known.

### **4.6 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.

### **4.7 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.

### **4.8 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 the Yellow Card Scheme at:  
[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

### **4.9 Overdose**

The symptoms of poisoning are epigastric burning, nausea and vomiting, dizziness, muscular weakness, miosis, tachycardia and the 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. In acute poisoning 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.

### **5.1 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.

**5.2 Pharmacokinetic properties**

After ingestion excretion of the Eucalyptus Oil takes place through the lungs, skin and kidneys.

**5.3 Preclinical safety data**

None.

**6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

None.

**6.2 Incompatibilities**

None known.

**6.3 Shelf life**

3 years unopened.

**6.4 Special precautions for storage**

Keep all medicines out of sight and reach of children.

Store below 25°C.

Keep container tightly closed.

**6.5 Nature and contents of container**

Glass bottle in 25ml and 50ml with a plastic cap.

**6.6 Special precautions for disposal**

None stated.

**7 MARKETING AUTHORISATION HOLDER**

Bell Sons and Company (Druggists) Limited

Gifford House  
Slaidburn Crescent  
Southport  
PR9 9AL

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 03105/0109

**9      DATE OF FIRST AUTHORISATION/RENEWAL OF THE  
AUTHORISATION**

25/05/2004

**10     DATE OF REVISION OF THE TEXT**

01/05/2016