

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Olbas Oil

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Ingredients</u>	<u>% w/w</u>
Cajuput Oil	18.50
Eucalyptus Oil	35.45
Methyl Salicylate	3.70
Clove Oil	0.10
Juniperberry Oil	2.70
Levomenthol	4.10
Mint Oil, Partly Dementholised	35.45

## 3 PHARMACEUTICAL FORM

Inhalation vapour, liquid.

Cutaneous liquid.

Pale green transparent liquid.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Inhalation Use:

For the relief of bronchial and nasal congestion caused by colds, catarrh, influenza and hayfever, rhinitis and minor infections of the respiratory tract.

Cutaneous Use

Symptomatic relief of muscular pain and stiffness, including backache, sciatica, lumbago, fibrositis and rheumatic pain.

### 4.2 Posology and method of administration

For inhalation use:

Adults and children aged 2 and over: Sprinkle 2 or 3 drops on a handkerchief, or add to hot water and inhale the vapours.

Children aged 3 months to 2 years: Sprinkle 1 drop on a tissue placed out of the child's reach.

Not recommended for babies under 3 months old.

For cutaneous use:

Adults and children aged 12 and over: Apply lightly to the painful area three times daily.

Not recommended for children under 12 years old.

### **4.3 Contraindications**

Hypersensitivity to the active substances.

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

If symptoms worsen or do not improve after 7 days, a doctor should be contacted.

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

No interaction studies have been performed.

In the literature, Methyl Salicylate has been reported to potentiate the anticoagulant effects of warfarin when applied topically.

### **4.6 Pregnancy and lactation**

There are no or limited amount of data from the use of Olbas Oil in pregnant women. Animal studies are insufficient with respect to reproductive toxicity. Olbas Oil should not be used during pregnancy unless potential benefits outweigh any risks.

It is unknown whether Olbas Oil /metabolites are excreted in human or animal milk. However, at therapeutic doses of Olbas Oil no effects on the breastfed newborns/infants are anticipated. Nevertheless it is not recommended that Olbas Oil be used during breast feeding.

### **4.7 Effects on ability to drive and use machines**

Olbas Oil has no influence on the ability to drive and use machines.

#### **4.8 Undesirable effects**

No undesirable effects are likely with this product because of the low concentrations of the active ingredients. However, local hypersensitivity, contact dermatitis and irritant effects of Levomenthol and Clove Oil are listed in the literature. Methyl Salicylate may cause heartburn, wheezing, dyspnoea and the worsening of asthma.

#### **4.9 Overdose**

Reports of an overdose by inhalation of 5 ml Olbas Oil have been said to cause ataxia, confusion, euphoria, nystagmus and diplopia.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Other Cold Combination Preparations, ATC code: R05X & Topical Products for Joint and Muscular Pain - Preparations with Salicylic Acid Derivatives, ATC code: M02A C

Cajuput Oil, Clove Oil, Eucalyptus Oil, Juniperberry Oil and Mint Oil, Partly Dementholised render secretions more fluid and relieve congestion. Topically they are rubefacient and mildly analgesic. Levomenthol relieves symptoms of bronchitis and sinusitis. Topically it is cooling and analgesic. Methyl Salicylate has analgesic properties. It is readily absorbed through the skin and relieves pain in lumbago, sciatica and rheumatic conditions.

#### **5.2 Pharmacokinetic properties**

When inhaled, the product is intended for local effect on the oropharynx. Excretion of essential oils takes place through the lungs, skin and kidneys. After absorption, Levomenthol is excreted in the urine and bile as glucuronide.

#### **5.3 Preclinical safety data**

Clove Oil, Eucalyptus Oil, Juniper Oil and Levomenthol are mild to moderate irritants of human skin. Clove Oil and Mint Oil, Partly Dementholised are irritant to mucous membranes at concentrations >3%. There are no other non-clinical data available that are of relevance to the prescriber that are not mentioned in other sections of the Summary of Product Characteristics.

### **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

This product contains no excipients

### **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**

Packaged into 10 ml, 12 ml, 15 ml, 20 ml, 25 ml, 28 ml or 30 ml amber glass bottles (Ph. Eur. type III glass) fitted with plastic dropper applicator and polypropylene tamper evident screw caps.  
Not all pack sizes may be marketed.

### **6.6 Special precautions for disposal**

Any unused product or waste material should be disposed of in accordance with local requirements.

## **7 MARKETING AUTHORISATION HOLDER**

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**8.    MARKETING AUTHORISATION NUMBER**

PL 01074/5029R

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

Date of first authorisation:   23 February 1984.

Date of latest renewal:        15 March 2005.

**10    DATE OF REVISION OF THE TEXT**

11/10/2018