

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Olbas for Children Inhalation Vapour, Liquid

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Ingredients</u>	<u>% w/w</u>
Cajuput Oil	4.625
Mint Oil, Partly Dementholised	8.863
Eucalyptus Oil	8.863
Levomenthol	1.025
Methyl Salicylate	0.925

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Inhalation vapour, liquid.  
Colourless to pale yellow transparent liquid.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

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

### 4.2 Posology and method of administration

For inhalation use.

Children aged 3 months to 2 years: Sprinkle 4 drops on to a tissue placed out of the child's reach.

Children aged 2 years and over: Sprinkle 8 to 12 drops on to a handkerchief, or add to hot water and inhale the vapours.

Not recommended for babies under 3 months old.

Do not use for topical application.

### 4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients.

### 4.4 Special warnings and precautions for use

Do not allow oil to remain in contact with skin for extended periods.  
If symptoms worsen or do not improve after 7 days, contact a doctor.

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

No interaction studies have been performed.

#### **4.6 Fertility, pregnancy and lactation**

Ask your doctor or pharmacist for advice before taking any medicine.

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

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

#### **4.8 Undesirable effects**

No undesirable effects have been reported.

#### **4.9 Overdose**

No cases of overdose have been reported.

### **5 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic properties**

Pharmacotheapeutic group: Other Cold Combination Preparations, ATC code: R05X  
Cajuput Oil, Clove Oil, Eucalyptus Oil, Juniper Oil and Mint Oil, Partly Dementholised are topically rubefacient and mildly analgesic. When inhaled, they render secretions more fluid and relieve congestion.

Levomenthol relieves symptoms of bronchitis and sinusitis, when inhaled, and is cooling and analgesic when applied topically

Methyl Salicylate is readily absorbed through the skin and relieves pain in lumbago, sciatica and rheumatic conditions.

#### **5.2 Pharmacokinetic properties**

No data.

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

No data.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Clove Oil  
Juniper berry Oil  
Isopropyl Myristate  
Orange Fragrance 170594

#### **6.2 Incompatibilities**

Not applicable.

#### **6.3 Shelf life**

3 years.

#### **6.4 Special precautions for storage**

Do not store above 25°C.  
Store in original package to protect from light

#### **6.5 Nature and contents of container**

10 ml, 15ml, 20ml, 25ml, 28 ml and 30ml filled into 10 ml, 15ml, 20ml, 25ml, 30ml and 30 ml respectively amber glass bottles fitted with plastic dropper applicator and polypropylene tamper evident screw caps.  
Not all pack sizes may be marketed.

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

No special requirements.

### **7 MARKETING AUTHORISATION HOLDER**

GR Lane Health Products Ltd  
Sisson Road  
Gloucester GL2 0GR  
United Kingdom

### **8 MARKETING AUTHORISATION NUMBER**

PA 257/15/4

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

Date of first authorisation:

### **10 DATE OF REVISION OF THE TEXT**

May 2013