SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Olbas Oil

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	%w/w
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.

Incorrect use or accidental exposure to Olbas Oil may be harmful. If the product is accidentally put into the nose or swallowed the patient should seek immediate medical advice.

If the product gets into the eyes or comes into direct contact with the surface of the eye(s) the patient should wash the eye(s) thoroughly and seek immediate medical advice.

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 concentration 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.

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 website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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, 12ml, 15 ml, 20 ml, 25 ml, 28 ml or 30 ml amber glass bottles (Ph. Eur. type III glass) fitted with a polyethylene dropper and polypropylene tamper-evident child resistant cap, with a polyethylene inner.
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

G. R. Lane Health Products Limited
Sisson Road
Gloucester
GL2 0GR
United Kingdom
Tel: +44 (0)1452 524012
Fax: +44 (0)1452 507930
Email: info@laneshealth.com

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

04/09/2024