

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Olbas Oil

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active substances</u>	<u>% w/w</u>
Cajuput Oil	18.50
Clove Oil	0.10
Eucalyptus Oil	35.45
Juniper Oil	2.70
Menthol	4.10
Mint Oil, Partly Dementholised	35.45
Methyl Salicylate	3.70

3 PHARMACEUTICAL FORM

Inhalation vapour, liquid
Cutaneous liquid
A pale green transparent liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an antiseptic, decongestant and analgesic for topical use in relief of nasal congestion and oropharyngeal inflammation and of pain due to muscular trauma.

4.2 Posology and method of administration

Inhalation:

Adults and children over 5 years: Sprinkle 2/3 drops on a handkerchief, or add to hot water and inhale the vapour.

Topical:

Apply lightly to the painful area 3 times daily.

4.3 Contraindications

- (i) Hypersensitivity to the active substances.
- (ii) Use on broken skin.
- (iii) Use in infants or young children under 5 years.

4.4 Special warnings and precautions for use

If there is no improvement or there is an aggravation of the condition consult the doctor.

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

There are no reports of adverse effects when used during pregnancy and lactation. Hence the product may be used.

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

Burns at application site, frequency: not known.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

No case of overdose has been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other Cold Combination Preparations, ATC code: R05X

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Cajuput Oil: Cineol is non toxic, non irritant and non sensitising at low doses.

Clove Oil: Clove oil is not considered to be toxic at the level of inclusion in Olbas Oil. Warnings are noted because of the Eugenol content regards alcoholism, anticoagulants, haemophilia, kidney disease, liver disease, paracetamol and prostatic cancer (Ref. Essential Oil Safety – A Guide for Health Care Professionals by Robert Tisserand/Tony Balacs, 1995).

Eucalyptus Oil: Eucalyptus Oil toxicity arises from ingestion of relatively large quantities (between 30 – 60 ml). This is not applicable to Olbas Oil.

Juniper Berry Oil: With an LD₅₀ of 5g/kg, Juniper berry Oil is regarded as non toxic. (Ref. Essential Oil Safety – A Guide for Health Care Professionals by Robert Tisserand/Tony Balacs, 1995).

Levomenthol: Large oral doses of levomenthol (above 0.2 g/kg) have been demonstrated to be hepatotoxic in rats. Overall, levomenthol is relatively non toxic, non sensitising but a possible mild irritant. It also causes hypersensitivity reactions including contact dermatitis in certain individuals.

The dosage level in Olbas Oil implies that its safety far outweighs the risks.

Mint Oil, Partly Dementholised: Relatively non toxic (Oral LD₅₀ in rat is 3 g/kg). It is non sensitising but possibly a mild irritant (Ref. Essential Oil Safety – A Guide for Health Care Professionals by Robert Tisserand/Tony Balacs, 1995). However, at the level of inclusion in Olbas Oil, the irritancy factor is not of a major concern.

Methyl Salicylate: Known to be teratogenic in rodents. This oil is moderately toxic and 4 to 8 ml is considered to be a lethal dose for children. The LD₅₀ is 1.2 g/kg (Ref. Essential Oil Safety – A Guide for Health Care Professionals by Robert Tisserand/Tony Balacs, 1995).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The 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.

Store in the original container with the cap tightly closed.

6.5 Nature and contents of container

Packaged into 10ml and 28ml amber glass bottle fitted with dropper/applicator and screw cap.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

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

7 MARKETING AUTHORISATION HOLDER

LanesHealth (Ireland) Limited
Suite 7, The Courtyard
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Sandyford
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Ireland

8 MARKETING AUTHORISATION NUMBER

PA22702/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st September 1988

Date of last renewal: 1st September 2008

10 DATE OF REVISION OF THE TEXT

June 2019