

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Olbas for Children

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Ingredients</u>	<u>% w/w</u>
Cajuput Oil	4.6250
Clove Oil	0.0250
Mint Oil, Partly Dementholised	8.8625
Eucalyptus Oil	8.8625
Juniper Oil	0.6750
Levomenthol	1.0250
Methyl Salicylate	0.9250

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, a doctor should be contacted.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Pregnancy and lactation

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

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

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 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

Cajuput Oil, Clove Oil, Eucalyptus Oil, Juniper Oil and Mint Oil, Partly Dementholised render secretions more fluid and relieve congestion. Levomenthol relieves symptoms of bronchitis and sinusitis. Methyl Salicylate has analgesic properties.

5.2 Pharmacokinetic properties

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

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.

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 01074/0012

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/07/2009

10 DATE OF REVISION OF THE TEXT

10/10/2018