SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Olbas Inhaler Nasal Stick

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	%w/w
Cajuput Oil	20
Levomenthol	40
Peppermint Oil	20
Eucalyptus Oil	20

3 PHARMACEUTICAL FORM

Nasal stick.
White tube closed with a white cap and containing a wad dosed with Olbas Inhaler oil.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of blocked up sinuses, catarrh, hay fever, colds and influenza.

4.2 Posology and method of administration

For nasal use.
Adults and children aged 6 and over: Insert into each nostril in turn and inhale whilst keeping the other nostril closed. Do not use more than four times per hour.
Not recommended for children under 6 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.

4.6 Pregnancy and lactation

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

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

4.7 Effects on ability to drive and use machines

Olbas Inhaler 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 are listed in the literature.

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 Nasal Decongestants, ATC code: R01A X
Cajuput Oil, Eucalyptus Oil and Peppermint Oil render secretions more fluid and relieve congestion.
Levomenthol relieves symptoms of bronchitis and sinusitis.

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

Eucalyptus Oil and Levomenthol are mild to moderate irritants of human skin. Peppermint Oil is 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

The product contains no excipients.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

White polypropylene tubes closed with a white LDPE plug and containing a cellulose acetate wad.
Pack size: 695 milligrams or 2 x 695 milligrams.
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 01074/0003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07/08/2006

10 DATE OF REVISION OF THE TEXT

20/01/2010