Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Olbas Pastilles

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1.7 g pastille contains:

Active substance(s)

Eucalyptus Oil	1.16	% w/w
Peppermint Oil	1.12	% w/w
Levomenthol	0.10	% w/w
Juniper Oil	0.067	% w/w
Methyl Salicylate	0.047	% w/w
Clove Oil	0.0025	% w/w

Excipients

Sucrose	39.80	% w/w
Glucose	9.80 – 14.00	% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pastille
Dull, green, oval, ribbed pastilles.

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

Adults and children aged 7 years and over:
Dissolve a pastille slowly in the mouth when required. Not more than 8 pastilles should be taken in any 24 hour period.

4.3 Contraindications

1. Use in infants or young children.
2. Hypersensitivity to the active substances or to any of the excipients.
3. Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase- isomaltase insufficiency should not take this medicine.

4.4 Special warnings and precautions for use

If there is no improvement or there is aggravation of the condition consult the 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

Data on a large number of exposed pregnancies indicate no adverse effects of Olbas Pastilles on pregnancy or on the health of the foetus/new-born child. To date, no other relevant epidemiological data are available.
Caution should be exercised when prescribing to pregnant women.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

No undesirable effects are likely with this product.

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

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Copper chlorophyllin (E141)
Liquid glucose
Pregelatinised starch (from tapioca and waxy maize)
Sucrose

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

45 g pastilles contained in a foil pouch integral with a carton.

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

7 MARKETING AUTHORISATION HOLDER

G. R. Lane Health Products Limited
Sisson Road
Gloucester
GL2 0GR
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 257/15/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 June 1996

Date of last renewal: 10 June 2006

10 DATE OF REVISION OF THE TEXT

January 2009