

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Olbas Inhaler nasal stick

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients, see section 6.1.

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, c atarrh, hay fever, colds and influenza.

4.2 Posology and method of administration

Insert into each nostril in turn and inhale whilst keeping the other nostril closed. May be used up to four times per hour as required.

4.3 Contraindications

Hypersensitivity to the active substances.
Use in infants and young children.

4.4 Special warnings and precautions for use

If symptoms persist, seek medical advice. Keep out of the sight and reach of children. Store below 25°C.

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 and hence the product may be used.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Contact dermatitis and other allergic reactions may occur in hypersensitive people.

4.9 Overdose

Reports of an overdose by inhalation of 5ml 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: R01AX

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Levomenthol: Levomenthol may give rise to hypersensitivity reactions including contact dermatitis. Cases of toxicity have been reported following ingestion. It is highly unlikely that the quantity of levomenthol included in Olbas Inhaler would cause any toxicity problems.

Peppermint Oil: Peppermint Oil may be an irritant and may rarely cause hypersensitivity reactions and headache. The level of peppermint oil in Olbas Inhaler is unlikely to give rise to any toxicity problems.

Cajuput Oil: Martindale Extra Pharmacopoeia 30th Edition does not list any toxicity concerns with Cajuput Oil. Again, the low level of the oil in Olbas Inhaler is unlikely to present any problems.

Eucalyptus Oil: Eucalyptus Oil toxicity arises from ingestion of relatively large quantities. This would not be possible with Olbas Inhaler.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25°C.
Keep the container tightly closed.

6.5 Nature and contents of container

Polypropylene tubes closed with a polypropylene/polyethylene co-polymer cap and containing a cellulose acetate wad dosed with 695 mg Olbas Inhaler oil.

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

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8 MARKETING AUTHORISATION NUMBER

PA22702/002/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 5 September 2007

10 DATE OF REVISION OF THE TEXT

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