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IRISH MEDICINES BOARD

PUBLIC ASSESSMENT REPORT FOR A MEDICINAL PRODUCT FOR HUMAN USE

Scientific discussion

Olbas for Children
PA0257/015/004

The Public Assessment Report reflects the scientific conclusion reached by the Irish Medicines Board (IMB) at the end of the evaluation process and provides a summary of the grounds for approval of a marketing authorisation for a specific medicinal product for human use. It is made available by the IMB for information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of Directive 2001/83/EC, as amended. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the IMB leading to the approval of the medicinal product for marketing in Ireland.

I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the IMB has granted a marketing authorisation for Olbas For Children Inhalation Vapour, Liquid. The product is a colourless to pale yellow transparent liquid containing; cajuput oil, eucalyptus oil, levomenthol, methyl salicylate and mint oil, from G.R. Lane Health Products Ltd. on 3rd August 2012. The therapeutic indication is for the relief of bronchial and nasal congestion caused by colds, catarrh, influenza and hay fever, rhinitis and minor infections of the respiratory tract when inhaled.

This application for a marketing authorisation was submitted in accordance with Article 10a of Directive 2001/83/EC and is referred to as a 'well established use' application. This means that the product has been in clinical use in the EU for at least ten years.

The Summary of Product Characteristics (SmPC) for this medicinal product is available on the IMB's website at www.imb.ie

Name of the product	Olbas for Children
Name(s) of the active substance(s) (INN)	cajuput oil eucalyptus oil levomenthol methyl salicylate mint oil, partly dementholised
Pharmacotherapeutic classification (ATC code)	R05X
Pharmaceutical form and strength(s)	Inhalation vapour liquid
Marketing Authorisation Number(s) in Ireland (PA)	PA0257/015/004
Marketing Authorisation Holder	G.R. Lane Health Products Ltd. UK

II QUALITY ASPECTS

II.1. Introduction

This application is for Olbas For Children Inhalation Vapour, Liquid.

II.2 Drug substance

The active substances are Cajuput oil, eucalyptus oil, levomenthol, mint oil, partly dementholised and methyl salicylate which are established active substances described in the European Pharmacopoeia and the British Pharmaceutical Codex, and are manufactured in accordance with the principles of Good Manufacturing Practice (GMP).

The active substance specifications are considered adequate to control the quality and meets current pharmacopoeial requirements. Batch analytical data demonstrating compliance with this specification has been provided.

II.3 Medicinal product

P.1 Composition

Olbas for Children is an inhalation vapour liquid and is a colourless to pale yellow transparent liquid.

The product contains the following active substances:

Active Substance	%w/w
Cajuput Oil BPC	4.625
Eucalyptus Oil Ph. Eur.	8.863
Levomenthol Ph. Eur.	1.025
Mint Oil, Partly Dementholised Ph. Eur.	8.863
Methyl Salicylate Ph. Eur.	0.925

The following are also present as excipients in the product: isopropyl myristate, orange fragrance 170594, clove oil and juniper berry oil.

P.2 Pharmaceutical Development

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

P.3 Manufacture of the Product

The product is manufactured in accordance with the principles of good manufacturing practice (GMP) at a suitably qualified manufacturing site.

The manufacturing process has been validated according to relevant European and ICH guidelines and the process is considered to be sufficiently validated.

P.4 Control of Other Substances (Excipients)

All excipients comply with the Ph. Eur. or are adequately controlled by the manufacturer's specifications.

P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for preparations for inhalation, and the tests and control limits are considered appropriate for this type of product.

The analytical methods used are described in sufficient detail and are supported by validation data.

Batch analytical data for a number of batches from the proposed production site have been provided, and demonstrate the ability of the manufacturer to produce batches of finished product of consistent quality.

P.6 Packaging material

The product is presented in amber glass bottles fitted with a plastic dropper applicator and polypropylene tamper evident screw caps. The bottles contain 10 ml, 15 ml, 20 ml, 25 ml, 28 ml or 30 ml of the product.

Evidence has been provided that glass bottles, dropper and screw caps comply with Ph. Eur. and EU legislation for use with foodstuffs requirements.

P.7 Stability of the Finished Product

Stability data on the finished product in the proposed packaging have been provided in accordance with EU guidelines demonstrating the stability of the product for 2 years when stored below 25°C in the original package to protect from light.

II.4 Discussion on Chemical, Pharmaceutical and Biological Aspects

The important quality characteristics of the product are well-defined and controlled. Satisfactory chemical and pharmaceutical documentation has been provided, assuring consistent quality of Olbas for Children.

III NON-CLINICAL ASPECTS

III.1 Introduction

This active substances have been available on the European/Irish market for more than ten years. Preclinical data have been superseded by clinical experience and therefore no preclinical assessment report is available.

IV CLINICAL ASPECTS

IV.1 Introduction

Olbas for Children contains a combination of active ingredients which have been in use as herbal remedies for many years. Eucalyptus oil has for over 150 years been known as a remedy for intermittent fever, catarrhal infections and bronchitis. Mint oil, partly dementholised has been widely used both for catarrh of the upper respiratory tract and externally in myalgia. Cajuput oil has been used extensively in the treatment of rheumatism, laryngitis and bronchitis. Among other indications levomenthol possesses the general properties of peppermint oil, but somewhat intensified and has been used both in upper respiratory tract infections and topically for the relief of local pain.When applied topically, methyl salicylate, which is the principal constituent of Oil of Wintergreen, is absorbed through skin for the relief of pain in rheumatic conditions.

Due to the nature of the application ‘well established use’ the company is exempt from the requirement to conduct clinical trials to demonstrate the safety and efficacy of the product. Instead reliance is placed on the published scientific literature and on extensive experience in clinical practice.

The content of the SmPC approved during the national procedure is considered appropriate to the nature of the active substances.

IV.5 Clinical Safety

The active ingredients of Olbas for Children are considered safe when taken by the inhalational route and even if accidentally or intentionally injested the quantities and strengths present in the product are unlikely to cause significant harm. Therefore routine pharmacovigilance measures have been agreed.

The Marketing Authorisation Holder submitted a set of documents describing the Pharmacovigilance System, including information on the availability of an EU Qualified Person for Pharmacovigilance (EU-QPPV) and the means for notification of adverse reaction reports in the EU or from a Third Country.

IV.6 Discussion on the clinical aspects

The active ingredients are well established and considered safe in the proposed indication.

V OVERALL CONCLUSIONS

Benefit/Risk Assessment and Recommendation

Olbas for Children contains a combination of volatile oils to be applied topically to the respiratory tract by the inhalational route. It is likely to provide symptomatic relief to symptoms caused by inflammation. It is considered to be a safe product even in cases of ingestion and the risk benefit balance is therefore positive.