Public Assessment Report

Sudafed Inhalant Oil

Eucalyptus Oil
Peppermint Oil
Racemic Camphor
Levomenthol

PL 00014/0659

The Boots Company Plc

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Lay Summary

The MHRA granted a Marketing Authorisation (licence) to The Boots Company PLC for the medicinal product Sudafed Inhalant Oil on 13th April 2007. The product was confirmed to be identical to the cross reference product Boots Herbal Inhalant Oil.

Scientific Discussion

INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted marketing authorisations for the medicinal product Sudafed Inhalant Oil (PL 00014/0659).

This was an abridged simple application made under Article 10.1c of EC Directive 2001/83, as amended, also known as an informed consent application. Sudafed Inhalant Oil is considered to be an identical product to that of Boots Herbal Inhalant Oil PL (00014/0336). The Marketing Authorisation Holder of the cross-referenced licences is also The Boots Company PLC and therefore they are in possession of all the data that are relevant to these applications.

Active Ingredients
Eucalyptus Oil, Peppermint Oil, Racemic Camphor, Levomenthol.

Menthol, eucalyptus, peppermint and camphor are volatile substances and are thought to produce an irritant effect on the respiratory tract, possibly via nasal/pulmonary arc.

Expert Report
Expert statements in relation to the quality, clinical and non-clinical aspects of the product confirming that they are identical to the cross-reference product are provided from suitably qualified persons.

Summary of Product Characteristics
The SPC was updated to bring it in to line with current requirement and can be found on page 7 of this report.

Leaflet, Labels and Packaging.
The leaflet and labels are combined for this type of product and can be found on page 8 of this report.

The marketing authorisation holder has provided a commitment to update the marketing authorisation with a package leaflet in compliance with Article 59 of Council Directive 2001/83/EC and that the leaflet shall reflect the results of consultation with target patient groups, no later than 1st July 2008.

ASSESSOR'S OVERALL CONCLUSIONS ON QUALITY AND ADVICE

A Marketing Authorisation was granted.

Overall Conclusion and Risk/Benefit Analysis

Quality

The quality aspects of the product were confirmed to be identical to the cross-reference product.

Pre-Clinical

No new preclinical data were submitted and none are required for applications of this type.

Clinical

The clinical aspects of the product were confirmed to be identical to the cross-reference product.

Risk/Benefit Analysis

The product was demonstrated to be identical to the cross-reference product and which has already been found to have a positive risk/benefit ratio.

Steps Taken During Assessment

1	The MHRA received the application on 09/06/2005.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 20/07/2005.
3	Following assessment of the application the MHRA requested further information from the applicant regarding the quality assessment on 23/11/2005 and 16/11/2006.
4	The applicant provided further information in regard to the quality assessment on 01/09/2006 and 14/02/2007.
5	The application was determined on 13/04/2007.

Steps Taken after Assessment

None

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Sudafed Inhalant Oil

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient	%w/w
Racemic Camphor	1.0
Eucalyptus Oil	50.0
Levomenthol	35.0
Peppermint oil	10.0

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Inhalation vapour, liquid
A clear, colourless or pale straw-coloured oil with a characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of nasal congestion.

4.2 Posology and method of administration

Adults and children over 2 years:
Place one or two drops of this product onto a handkerchief or tissue and inhale vapours deeply.

Alternatively add one or two drops to a pint of water and inhale.
Use as required.

Use in the Elderly:
There have been no specific studies of the use of this product in the elderly. It is unnecessary to modify the method of administration for use in the elderly.
Children under two years:
Not recommended for children under two years.

For inhalation.

4.3 Contraindications

Hypersensitivity to the product or any of the excipients.
Do not use in children under 2 years of age.

4.4 Special warnings and precautions for use

Avoid contact with the eyes and prolonged contact with the skin.
If symptoms persist for more than 3 days, consult your doctor.
Do not put drops directly into the nose or mouth.
Keep all medicines out of the reach and sight of children.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed, but no clinically significant interactions are expected.

4.6 Pregnancy and lactation

Pregnancy

There are no adequate data from the use of Racemic Camphor, Eucalyptus Oil, Levomenthol or Peppermint oil in pregnant women.
Sudafed Inhalant Oil should not be used in pregnancy unless clearly necessary.

Lactation

It is unknown whether Racemic Camphor, Eucalyptus Oil, Levomenthol or Peppermint oil are excreted in human breast milk. The excretion of Racemic Camphor, Eucalyptus Oil, Levomenthol and Peppermint oil in milk has not been studied in animals. A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with Sudafed Inhalant Oil should be made taking into account the benefit of breast-feeding to the child and the benefit of Sudafed Inhalant Oil therapy to the woman.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

Rarely, hypersensitivity reactions.

4.9 Overdose

Symptoms following ingestion may include hypersensitivity reactions, erythematous skin rash, nausea, vomiting, headache, bradycardia, muscle tremor, severe abdominal pain, epigastric burning, vertigo, ataxia, drowsiness,

delirium, miosis, cyanosis, pulmonary damage, convulsions, CNS depression and coma.

Treatment consists of gastric lavage and the administration of activated charcoal by mouth. Convulsions may be controlled by the slow intravenous administration of diazepam. Alternative anticonvulsants such as phenobarbital or phenytoin may also be required.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: R05X

Menthol, eucalyptus, peppermint and camphor are volatile substances and are thought to produce an irritant effect on the respiratory tract, possibly via nasal/pulmonary arc.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl salicylate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Amber glass bottle with polythene plug and child resistant closure (polypropylene inner with expanded polythene wad).
Pack size: 10ml.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

The Boots Company PLC
1 Thane Road West
Nottingham NG2 3AA

Trading as: BCM

8 MARKETING AUTHORISATION NUMBER(S)

PL 00014/0659

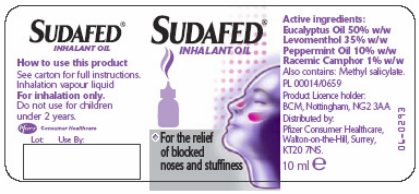
9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

13/04/2007

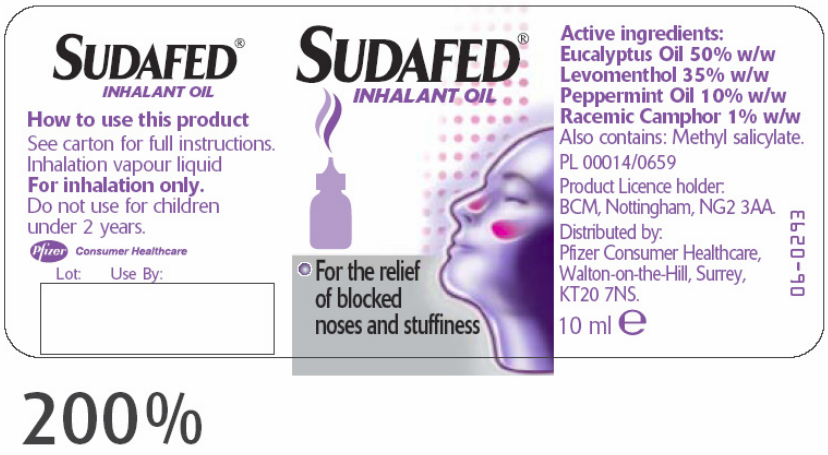
10 DATE OF REVISION OF THE TEXT

13/04/2007

Labels and Leaflet


SUDAFED®
INHALANT OIL
How to use this product
See carton for full instructions.
Inhalation vapour liquid
For inhalation only.
Do not use for children under 2 years.
Consumer Healthcare
Lot: Use By:
SUDAFED®
INHALANT OIL
For the relief of blocked noses and stuffiness
Active ingredients:
Eucalyptus Oil 50% w/w
Levomenthol 35% w/w
Peppermint Oil 10% w/w
Racemic Camphor 1% w/w
Also contains: Methyl salicylate.
PL 00014/0659
Product Licence holder:
BCM, Nottingham, NG2 3AA.
Distributed by:
Pfizer Consumer Healthcare,
Walton-on-the-Hill, Surrey,
KT20 7NS.
10 ml e
06-0293

100%


SUDAFED®
INHALANT OIL
How to use this product
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Inhalation vapour liquid
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10 ml e
06-0293

200%