CROOKES VAPOUR RUB FOR CHILDREN
(racemic camphor, levomenthol, eucalyptus oil)

PL 00327/0178

UKPAR

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Crookes Vapour Rub For Children
(racemic camphor, levomenthol, eucalyptus oil)

PL 00327/0178

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Crookes Healthcare Limited a Marketing Authorisation (licence) for the medicinal product, Crookes Vapour Rub For Children (PL 00327/0178), on 11th August 2010. This is a medicine available on the General Sales List (GSL), and can be purchased at pharmacies, supermarkets and other retail outlets without the supervision of a pharmacist.

Crookes Vapour Rub For Children is used to enable clear and easy breathing in children suffering from head colds, stuffy nose, coughs and chest colds.

This application is considered to be identical to a previously granted licence for Boots Mild Vapour Rub 3 Months Plus / Boots Children’s 3 Months Plus Vapour Rub (PL 00014/0562), authorised to The Boots Company PLC on 31st May 1996. The proposed and reference products are identical.

No new or unexpected safety concerns arose from this application and it was therefore judged that the benefits of Crookes Vapour Rub For Children outweigh the risk; hence a Marketing Authorisation has been granted.
Crookes Vapour Rub For Children
(racemic camphor, levomenthol, eucalyptus oil)

PL 00327/0178

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Crookes Healthcare Limited a Marketing Authorisation for the medicinal product, Crookes Vapour Rub For Children (PL 00327/0178), on 11th August 2010. The product is available on a General Sales Licence (GSL).

This is a simple, abridged, ‘informed consent’ application submitted according to Article 10(c) of EC Directive 2001/83 (as amended), cross-referencing the Marketing Authorisation for Boots Mild Vapour Rub 3 Months Plus / Boots Children’s 3 Months Plus Vapour Rub (PL 00014/0562), licensed to The Boots Company PLC on 31st May 1996.

Crookes Vapour Rub For Children is used to enable clear and easy breathing in children suffering from head colds, stuffy nose, coughs and chest colds.

No new data were submitted nor was it necessary for this simple application, as the data are identical to that of the previously granted cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no PAR was generated for it.
1. INTRODUCTION

This is a simple abridged application, submitted under Article 10c of Directive 2001/83/EC (as amended) for Crookes Vapour Rub For Children. The proposed Marketing Authorisation Holder (MAH) is Crookes Healthcare Limited.

The reference product is Boots Mild Vapour Rub 3 Months Plus / Boots Children’s 3 Months Plus Vapour Rub (PL 00014/0562), authorised to The Boots Company PLC on 31st May 1996. The proposed and reference products are identical.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The approved name of the product is Crookes Vapour Rub For Children. The product name is accepted.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

Crookes Vapour Rub For Children is presented as an ointment for topical administration, to be used on the chest and back, and contains the active ingredients, racemic camphor, levomenthol and eucalyptus oil. Each 1g of ointment contains 60mg of racemic camphor, 10mg of levomenthol and 15mg eucalyptus oil. The medicinal product is licensed for marketing in the following containers (full details are provided in the SmPC):

   i) An amber glass jar containing 45g of ointment with either a tin plate cap, with waxed aluminium-faced pulpboard liner, or with a thermoset plastic cap

   ii) A polystyrene jar with an unlined polypropylene cap containing 25g or 45g of ointment

The container closure systems and pack sizes are the same as those for the reference product.

The approved shelf-life (36 months for glass jar, 20 months for polystyrene jar) and storage conditions (‘None’ for glass jar, ‘Do not store above 25°C’ for polystyrene jar) are identical to the details registered for the cross-reference product.
2.3 Legal status
The product is a GSL licensed medicine, available by supply through pharmacies, supermarkets and other retail outlets without the need for supervision by a pharmacist.

2.4 Marketing Authorisation Holder / Contact Persons / Company
The proposed Marketing Authorisation Holder is ‘Crookes Healthcare Limited, 1 Thane Road West, Nottingham NG2 3AA, UK’.

The Qualified Person (QP) responsible for pharmacovigilance was stated and their CV included.

2.5 Manufacturers
The proposed manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed composition is identical to the details registered for the cross-reference product.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference product and the maximum batch size is stated.

2.8 Finished product / shelf-life specification
The proposed finished product specification is consistent with the details registered for the cross-reference product.

2.9 Drug substance specification
The proposed drug substance specification is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance
There are no materials of human or animal origin contained in, or used in the manufacturing process for, the proposed product. None of the excipients are sourced from genetically modified organisms.

3. EXPERT REPORT
A satisfactory quality overall summary has been prepared by an appropriately qualified expert. The CV of the expert was provided.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product name. The appearance of the product (smooth, translucent, white ointment) is identical to that of the cross-reference product.
5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The approved SmPC is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL) / LABELLING

PIL

No PIL has been provided. There is no package leaflet for this medicinal product as all relevant information has been included on the label.

Labelling

The labelling texts are satisfactory. The MAH has submitted text versions only and has committed to submitting mock-up labelling to the relevant regulatory authorities for approval before packs are marketed.

7. CONCLUSIONS

The grounds for this application are considered adequate. A Marketing Authorisation was therefore granted.
NON-CLINICAL ASSESSMENT

This is a simple, abridged, ‘informed consent’ application made under Article 10(c) of EC Directive 2001/83 (as amended).

No new non-clinical data have been supplied with this application and none are required for an application of this type. A non-clinical overview has been written by a suitably qualified person and is satisfactory. The CV of the non-clinical expert has been supplied.
CLINICAL ASSESSMENT

This is a simple, abridged, ‘informed consent’ application made under Article 10(c) of EC Directive 2001/83 (as amended), cross-referring to the Marketing Authorisation for Boots Mild Vapour Rub 3 Months Plus / Boots Children’s 3 Months Plus Vapour Rub (PL 00014/0652).

No new clinical data have been supplied with the application, and none are required for applications of this type. A clinical overview has been written by a suitably qualified person and is satisfactory. The CV of the clinical expert has been supplied.
OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

QUALITY
The data for this application are consistent with those previously assessed for the cross-reference product and as such have been judged to be satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for an application of this type.

EFFICACY
This application is considered identical to the previously granted licence for Boots Mild Vapour Rub 3 Months Plus / Boots Children’s 3 Months Plus Vapour Rub (PL 00014/0652, The Boots Company PLC).

No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE
The approved SmPC is satisfactory and consistent with the details registered for the cross-reference product.

No Patient Information Leaflet has been provided as the labelling text includes all the relevant information that would be presented in the PIL. The information stated in the labelling text is satisfactory and consistent with the SmPC.

The MAH has submitted text versions only and has committed to submitting mock-up labelling to the relevant regulatory authorities for approval before packs are marketed.

BENEFIT-RISK ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product. The benefit: risk ratio is considered to be positive.
Crookes Vapour Rub For Children
(racemic camphor, levomenthol, eucalyptus oil)

PL 00327/0178

STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the Marketing Authorisation application on 5th June 2003

2 Following standard checks and communication with the applicant the MHRA considered the application valid on 4th July 2003

3 Following assessment of the application the MHRA requested further information relating to the quality dossier on 2nd October 2003, 22nd December 2003 and 20th August 2004

4 The applicant responded to the MHRA’s requests, providing further information for the quality sections on 24th October 2003, 17th March 2004 and 25th November 2004 respectively, and on 9th August 2010

5 The application was determined on 11th August 2010
Crookes Vapour Rub For Children
(racemic camphor, levomenthol, eucalyptus oil)

PL 00327/0178

STEPS TAKEN AFTER AUTHORISATION

Not applicable
SUMMARY OF PRODUCT CHARACTERISTICS
The UK Summary of Product Characteristics (SmPC) for Crookes Vapour Rub For Children is as follows:

1 NAME OF THE MEDICINAL PRODUCT
Crookes Vapour Rub For Children

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Racemic Camphor 6.0 %w/w
Levomenthol natural or synthetic 1.0 %w/w
Eucalyptus Oil 1.5 %w/w

For excipients, see 6.1

3 PHARMACEUTICAL FORM
An ointment

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
For head colds, stuffy nose, cough and chest colds

4.2 Posology and method of administration
For topical administration

For children over 3 months and adults: To be used on the chest and back particularly at bedtimes. Massage gently. Use sparingly on infants and young children. Apply a moderate amount on older children and adults.

Elderly: There is no need for dosage reduction in the elderly.

For children under 3 months: Not recommended for children under 3 months of age.

4.3 Contraindications
Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use
For external use only.

Keep all medicines out of the reach of children.

Not recommended for children under 3 months.

4.5 Interaction with other medicinal products and other forms of interaction
No clinically significant drug interactions are known.

4.6 Pregnancy and lactation
The safety of Crookes Vapour Rub For Children during pregnancy and lactation has not been established, but its use during these periods is not considered to constitute a hazard.
4.7 **Effects on ability to drive and use machines**
No adverse effects known.

4.8 **Undesirable effects**
Occasional hypersensitivity and irritant skin reactions.

4.9 **Overdose**
Following oral ingestion, symptoms of overdosage may include nausea, vomiting, colic, headache, dizziness, a feeling of warmth, delirium, muscle twitching, epileptiform convulsions, depression of the central nervous system and coma. Breathing may be difficult. There may be haematuria and albuminuria. Treatments consist initially of emptying the stomach by lavage and aspiration.

A purgative, such as sodium sulphate, 30g in 250ml of water, should be given. Convulsions may be controlled by intravenous administration of diazepam 5-10mg.

5 **PHARMACOLOGICAL PROPERTIES**

5.1 **Pharmacodynamic properties**
Eucalyptus oil, camphor, levomenthol are volatile substances and are thought to produce an irritant effect on the respiratory tract, probably via a nasal/pulmonary arc.

5.2 **Pharmacokinetic properties**
None stated.

5.3 **Preclinical safety data**
There are no pre-clinical data available specific to the product.

6 **PHARMACEUTICAL PARTICULARS**

6.1 **List of excipients**
White Soft Paraffin

6.2 **Incompatibilities**
None stated.

6.3 **Shelf life**
36 months in amber glass jar.
20 months in polystyrene.

6.4 **Special precautions for storage**
Amber glass jar: None
Polystyrene jar: Do not store above 25°C.

6.5 **Nature and contents of container**
An amber glass jar with either a tin plate cap with waxed aluminium faced pulpboard liner containing 45g with a thermoset plastic cap.
Or

A polystyrene jar with an unlined polypropylene cap containing 25g or 45g

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Crookes Healthcare Limited
1 Thane Road West
Nottingham NG2 3AA
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00327/0178

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11/08/2010

10 DATE OF REVISION OF THE TEXT

11/08/2010
LABELLING - text

Carton

Panel 1

CROOKES VAPOUR RUB FOR CHILDREN

For clear and easy breathing with head colds, stuffy nose, coughs and chest colds

45g

Panel 2

How to use Crookes Vapour Rub For Children

Check that carton seal is not broken before first use.

For children over 3 months and adults: To be used on the chest and back, especially at bedtime. Massage gently. Use sparingly on infants and young children. Apply a moderate amount on older children and adults.

Do not use on children under 3 months.

If symptoms do not go away talk to your doctor or pharmacist

Do not use if allergic to any of the ingredients.

This medicine may on rare occasions cause skin irritation. If concerned or anything else unusual happens, talk to your pharmacist or doctor.

FOR EXTERNAL USE ONLY

KEEP ALL MEDICINES OUT OF THE SIGHT AND REACH OF CHILDREN

Panel 2

CROOKES VAPOUR RUB FOR CHILDREN

Active ingredients:
Camphor Ph Eur 6.0% w/w, Eucalyptus Oil Ph Eur 1.5 % w/w,
Levonathol Ph Eur 1.0% w/w

Also contains White Soft Paraffin.

Do not store above 25°C

PL 00327/0178

Licence holder Crookes Healthcare Limited, Nottingham NG2 3AA
Manufactured by: The Boots Company PLC, Nottingham NG2 3AA

Lot

Use by

Text revised May 03

Carton Top
CROOKES VAPOUR RUB FOR CHILDREN

For clear and easy breathing with head colds, stuffy nose, coughs and chest colds

E 45g

How to use Crookes Vapour Rub For Children

For children over 3 months and adults:
To be used on the chest and back, especially at bedtime. Massage gently.
Use sparingly on infants and young children. Apply a moderate amount on older children and adults.

If symptoms do not go away, consult your doctor or pharmacist

FOR EXTERNAL USE ONLY

For full instructions, see carton.
KEEP ALL MEDICINES OUT OF THE SIGHT AND REACH OF CHILDREN

Active ingredients: Racemic Camphor Ph.Eur 6.0% w/w, Eucalyptus Oil Ph.Eur 1.5% w/w, Levomenthol Ph.Eur 1.0% w/w

Also contains White Soft Paraffin

Do not store above 25°C.

PL 00327/0178
Licence holder: Crookes Healthcare Limited, Nottingham NG2 3AA, UK.
Manufactured by The Boots Company PLC, Nottingham NG2 3AA, UK.

The batch number and expiry date will be overprinted in this area of the label

Text revised May 2003