Safeguarding public health

MHRA

# Public Assessment Report

## Boots Hexylresorcinol 2.4mg Throat Lozenges Blackcurrant

## PL 00014/0661

Medicines and Healthcare products Regulatory Agency

# BOOTS HEXYLRESORCINOL 2.4MG THROAT LOZENGES BLACKCURRANT

## PL 00014/0661

## UKPAR

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# BOOTS HEXYLRESORCINOL 2.4MG THROAT LOZENGES BLACKCURRANT

## PL 00014/0661

## LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) has granted The Boots Company plc a Marketing Authorisation (licence) for the medicinal product Boots Hexylresorcinol 2.4mg Throat Lozenges Blackcurrant (PL 00014/0661). This is a general sale list (GSL) medicine for the relief of sore throat.

Boots Hexylresorcinol 2.4mg Throat Lozenges Blackcurrant contains hexylresorcinol which numbs pain in the mouth and throat and is also a mild antiseptic.

This application is a duplicate of a previously granted licence for Crookes Hexylresorcinol Throat Lozenges E (PL 00014/0649).

No new or unexpected safety concerns arose from this simple application and it was therefore judged that the benefits of using Boots Hexylresorcinol 2.4mg Throat Lozenges Blackcurrant outweigh the risks, hence a Marketing Authorisation has been granted.

# BOOTS HEXYLRESORCINOL 2.4MG THROAT LOZENGES BLACKCURRANT

# PL 00014/0661

## SCIENTIFIC DISCUSSION

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# INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Boots Hexylresorcinol 2.4mg Throat Lozenges Blackcurrant (PL 00014/0661) to The Boots Company plc on 28 March 2006. The product is a general sale list (GSL) medicine.

This application was submitted as a simple abridged application according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Crookes Hexylresorcinol Throat Lozenges E (PL 00014/0649, approved on 22 September 2004).

No new data were submitted for this simple application, nor were any necessary, as the data are identical to that of the previously granted cross-referenced product. As the cross-referenced product was granted prior to the introduction of current legislation, no public assessment report was generated for it.

The product contains the active ingredient hexylresorcinol. Hexylresorcinol is a local anaesthetic for topical use on the mucous membranes of the mouth and throat. Mild antiseptic activity has also been demonstrated.

Boots Hexylresorcinol 2.4mg Throat Lozenges Blackcurrant is used as an antiseptic and local anaesthetic for the relief of sore throat and its associated pain.

# PHARMACEUTICAL ASSESSMENT

| | |
|---|---|
| **LICENCE NUMBER:** | **PL 00014/0661** |
| **PROPRIETARY NAME:** | **Boots Hexylresorcinol 2.4mg Throat Lozenges Blackcurrant** |
| **ACTIVE INGREDIENT(S):** | **Hexylresorcinol** |
| **COMPANY NAME:** | **The Boots Company plc** |
| **LEGAL STATUS:** | **GSL** |

## INTRODUCTION

This is a simple abridged application, submitted under Article 10c (formerly Article 10.1[a][i]) of Directive 2001/83/EC (as amended) for Boots Hexylresorcinol Throat Lozenges Blackcurrant. The reference product is Crookes Hexylresorcinol Throat Lozenges E (PL 00014/0649), held by The Boots Company plc. The test and reference products are identical.

A letter of access is not required as the authorisation holder is cross referring to its own licence.

The finished product manufacturers, assemblers, quality control and batch release sites are named. Valid copies of the manufacturing licences are provided. The finished product specification and manufacturing process is identical to that of the reference product.

There are no excipients of animal origin.

## EXPERT REPORTS

Satisfactory expert reports and *curriculum vitae* of experts are provided.

## PRODUCT LITERATURE

### Summary of Product Characteristics (SPC)

Satisfactory.

### Labelling

Satisfactory.

### PIL

A separate PIL is not provided with the packaging.

## MARKETING AUTHORISATION APPLICATION (MAA) FORM

Satisfactory.

## RECOMMENDATION

Grant of a Marketing Authorisation is acceptable.

# PRECLINICAL ASSESSMENT

No new preclinical data have been supplied with this application and none are required for an application of this type.

# CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for an application of this type.

# OVERALL CONCLUSION AND RISK-BENEFIT ASSESSMENT

## QUALITY

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

## PRECLINICAL

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

## EFFICACY

This application is identical to a previously granted application for Crookes Hexylresorcinol Throat Lozenges E.

No new or unexpected safety concerns arose from this application.

The SPC and combined PIL-labelling are satisfactory and consistent with those of the cross-referenced product.

## RISK-BENEFIT ASSESSMENT

The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The applicant's product is identical to the cross-referenced product. The risk-benefit assessment is therefore considered to be favourable.

# BOOTS HEXYLRESORCINOL 2.4MG THROAT LOZENGES BLACKCURRANT

## PL 00014/0661

## STEPS TAKEN FOR ASSESSMENT

| | |
|---|---|
| 1 | The MHRA received the marketing authorisation application for Boots Hexylresorcinol 2.4mg Throat Lozenges Blackcurrant on 30 November 2005. |
| 2 | Following standard checks the MHRA informed the applicant that its application was considered valid on 31 January 2006. |
| 3 | The MHRA's assessment of the submitted data was completed on 2 February 2006. |
| 4 | Further information was requested from the company on 2 February 2006. |
| 5 | The applicant submitted its response to further information request on 15 March 2006. |
| 6 | The MHRA completed its assessment of the application on 21 March 2006. |
| 7 | The application was determined on 28 March 2006. |

# BOOTS HEXYLRESORCINOL 2.4MG THROAT LOZENGES BLACKCURRANT

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## STEPS TAKEN AFTER AUTHORISATION - SUMMARY

| Date submitted | Application type | Scope | Outcome |
|---|---|---|---|
| | | | |
| | | | |
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# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Boots Hexylresorcinol 2.4mg Throat Lozenges Blackcurrant

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

| | mg per lozenge |
|---|---|
| Hexylresorcinol | 2.4 |

For full list of excipients, see Section 6.1

## 3 PHARMACEUTICAL FORM

Lozenge.
A round purple lozenge

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

As an antiseptic and local anaesthetic for the relief of sore throat and its associated pain.

### 4.2 Posology and method of administration

For oral administration.
Adults, the elderly and children 6 years and over: One lozenge dissolved slowly in the mouth every three hours or as required.
Do not take more than 12 lozenges in 24 hours.
Do not give to children under 6 years.

### 4.3 Contraindications

Hypersensitivity to any of the ingredients.

### 4.4 Special warnings and precautions for use

The label will convey:
Do not exceed the stated dose.

Keep all medicines out of the sight and reach of children
Not to be given to children under 6 years.
Each lozenge contains 1.1g of glucose and 1.4g of sucrose. This should be taken into account in patients with diabetes mellitus.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorbtion or sucrase-isomaltase insufficiency should not take this medicine.
The colour carmoisine (E122) may cause an allergic reactions.

## 4.5 Interactions with other medicinal products and other forms of interaction

None known.

## 4.6 Pregnancy and lactation

There is a lack of evidence of safety of the product in human pregnancy. But hexylresorcinol has been used widely for many years without apparent ill consequence. However, as with all medicines, caution should be exercised during pregnancy and lactation.

## 4.7 Effects on ability to drive and to use machines

No adverse effects known.

## 4.8 Undesirable effects

None known.

## 4.9 Overdose

Hexylresorcinol overdosage may cause minor gastrointestinal irritation. Treatment would be withdrawal of the product and symptomatic measures as appropriate.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Hexylresorcinol is local anaesthetic for topical use on the mucous membranes of the mouth and throat. Mild antiseptic activity has also been demonstrated. The product base has a demulcent action.

ATC code: R02A A12

## 5.2 Pharmacokinetic properties

Pharmacokinetic considerations do not arise since the pharmacological action is local to the oropharyngeal cavity.

## 5.3 Preclinical safety data

There are no pre-clinical data available specific to the product.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Liquid sucrose
Liquid glucose
Blackcurrant flavour
Levomenthol
Carmoisine edicol (E122)
Patent blue V (E131)

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf life

24 months

## 6.4 Special precautions for storage

Do not store above 25$^{o}$C

## 6.5 Nature and contents of container

Blister packs of 250 micron PVC / 40 gsm PVdC heat sealed to 20 micron hard temper aluminium foil.
Pack size: 24 lozenges.

## 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

None specific to the product/pack.

## 7 MARKETING AUTHORISATION HOLDER

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

## 8 MARKETING AUTHORISATION NUMBER

PL 00014/0661

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28/03/2006

## 10 DATE OF REVISION OF THE TEXT

28/03/2006

Combined Labelling and Patient Information Leaflet

# BOOTS HEXYLRESORCINOL 2.4MG THROAT LOZENGES BLACKCURRANT

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| PACK MOCK UP | | | STATUS |
|---|---|---|---|
| THE BOOTS COMPANY STRATEGIC MARKETING UNIT | PRODUCT NAME Boots Hexylresorcinol Throat Lozenges Blackcurrant | PL No. 00014/0661 | INTERNALLY APPROVED |
| | WORDING REF Internally approved 29/07/05 Vs.1 | | |

| VERSION No. | DATE ISSUED | REASON FOR CHANGE |
|---|---|---|
| 2 | 8/03/06 | Cross - referral - RFI |

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| PACK MOCK UP | | | STATUS |
|---|---|---|---|
| THE BOOTS COMPANY STRATEGIC MARKETING UNIT | PRODUCT NAME Boots Hexylresorcinol Throat Lozenges Blackcurrant | PL No. 00014/0661 | INTERNALLY APPROVED |
| | WORDING REF Internally approved vs1 dated 4/07/05 | | |

| VERSION No. | DATE | REASON FOR CHANGE |
|---|---|---|
| 2 | 29/07/05 | Cross-Referral |