Beechams Chesty Cough Oral Solution

PL 00079/0663

UKPAR

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Beechams Chesty Cough Oral Solution

PL 00079/0663

LAY SUMMARY

On 17th May 2011, the MHRA granted a Marketing Authorisation (licence) for the medicinal product Beechams Chesty Cough Oral Solution (PL 00079/0663). This product is a General Sale Licence (GSL).

The licence was granted to the company Beecham Group PLC., trading as GlaxoSmithKline Consumer Healthcare Limited. This company is the marketing authorisation holder.

This medicine is used for the short term relief of the symptoms of dry, tickly or scratchy coughs and sore throats. The medicine contains three active ingredients. Guaifenesin is an expectorant which loosens phlegm and relieves a chesty cough. Glucose liquid and treacle soothe and protect the surface of the mouth and throat to relieve their symptoms.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Beechams Chesty Cough Oral Solution outweigh the risks; hence Marketing Authorisation has been granted.

Beechams Chesty Cough Oral Solution

PL 00079/0663

SCIENTIFIC DISCUSSION

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INTRODUCTION

The Medicines and Healthcare Products Regulatory Agency (MHRA) granted a marketing authorisation (licence) for medicinal product Beechams Chesty Cough Oral Solution (PL 00079/0663) to Beecham Group PLC., trading as GlaxoSmithKline Consumer Healthcare on the 17th May 2011. This General Sale Licence (GSL) is used for the symptomatic relief of coughs (including bronchial cough) and chesty catarrh, particularly associated with colds and flu. The product also has a soothing, protective, demulcent action on a sore, irritated, tickling and inflamed throat.

This application was submitted as simple application according to Article 10c of Directive 2001/83/EC as amended, for a duplicate of the licence Beechams Veno's Expectorant (PL 00079/0208) held by the applicant.

No new data were submitted nor were they necessary for this simple application, as the data are identical to those of the previously granted duplicate licence.

A pharmacovigilance system has been provided with this application and is satisfactory. A suitable justification for non-submission of the Risk Management Plan has been provided.

No environmental risk assessment (ERA) has been undertaken, as this is not considered necessary. This product is essentially similar and the therapeutic indications and posology of the finished product are the same as those already licensed product. The applicant's justification for absence of ERA is satisfactory.

PHARMACEUTICAL ASSESSMENT

LICENCE NO: PL 00079/0663
PROPRIETARY NAME: Beechams Chesty Cough Oral Solution
COMPANY NAME: Beecham Group PLC
E.C. ARTICLE: Article 10c of Directive 2001/83/EC
LEGAL STATUS: GSL

1 INTRODUCTION

This is a simple, informed consent application for Beechams Chesty Cough Oral Solution, submitted under Article 10c of Directive 2001/83/EC as amended for a duplicate of the licence Beechams Veno's Expectorant (PL 00079/0208), approved on 31st January 1983 to the same marketing authorisation holder. The current application is considered valid.

2 MARKETING AUTHORISATION APPLICATION (MAA)

2.1 Name(s)

The proposed name of the product is Beechams Chesty Cough Oral Solution.
The product has been named in line with current requirements.

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

The product contains active ingredients guaifenesin, glucose liquid and treacle.

The solution is contained in amber cylinderical glass bottle fitted with a child resistant and tamper evident plastic screw cap with a pack size of 100 or 160ml.

The packaging and pack sizes are the same as those for the reference product.

The proposed shelf life is 3 years (unopened) or 6 months (once opened) with no special storage condition. The shelf-life and storage condition are identical to those for the reference product and are satisfactory.

2.3 Legal status

This product is a General Sale Licence (GSL).

2.4 Marketing authorisation holder/Contact Persons/Company

The proposed Marketing Authorisation holder is Beecham Group p.l.c., trading as: GlaxoSmithKline Consumer Healthcare, 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom.

The Qualified Person (QP) responsible for pharmacovigilance is stated and a CV is included.

2.5 Manufacturers

The proposed manufacturing sites are consistent with those registered for the reference product and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed composition is consistent with the details registered for the reference product.

2.7 Manufacturing process

The proposed manufacturing process is consistent with the details registered for the reference product and the maximum full scale batch size is stated.

2.8 Finished product/shelf-life specifications

The proposed finished product and shelf-life specification are in line with the details registered for the reference product.

2.9 Drug substance specification

The proposed drug substance specifications conform to the current European Pharmacopoeia monograph for guaifenesin, glucose liquid and treacle and are in-line with those for the reference product.

European Directorate for the Quality of Medicines (EDQM) certificates of suitability for the manufacturer of guaifenesin has been provided. The active substance manufacturers are in line with those for the reference product.

2.10 TSE Compliance

No materials of human or animal origin have been used in the manufacture of this product. This is consistent with the reference product.

2.11 Bioequivalence

No bioequivalence data are required to support this informed consent application, as the proposed product is manufactured to the same formula utilising the same process as the reference product Beechams Veno's Expectorant (PL 00079/0208).

3 EXPERT REPORT

The applicant has included detailed expert reports of the application. Signed declarations and copies of the experts' CVs are enclosed for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE

See 2.1 for details of the proposed product name. The appearance of the product is identical to that of the reference product.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The proposed SmPCs are consistent with the details registered for the reference product.

6. PATIENT INFORMATION LEAFLET (PIL)/LABELLING

User testing of the package leaflet has been accepted, based on a bridging report provided by the applicant making reference to the user-testing of the PIL for Piriton Syrup (PL 00036/0088). A critical analysis demonstrated that the key messages for

safe and effective use for all leaflets were similar. The justification on the rationale for bridging is accepted.

7. CONCLUSIONS

The data submitted with the application are acceptable. The grant of marketing authorisation is recommended.

PRECLINICAL ASSESSMENT

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

CLINICAL ASSESSMENT

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

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application are consistent with those previously assessed for the reference 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 the previously granted application for Beechams Veno's Expectorant (PL 00079/0208), granted to Beecham Group plc on 31st January 1983.

Pharmaceutical, preclinical and clinical expert statements have been provided, together with CVs showing the experts are appropriately qualified. The experts confirm that the product is identical in composition, manufacture and pharmaceutical characteristics to the respective reference product and that there are no toxicological or clinical issues.

No new or unexpected safety concerns arise from this application.

The SmPC, PIL and labelling are satisfactory and consistent with those for the reference 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 reference product. Extensive clinical experience with guaifenesin, glucose liquid and treacle is considered to have demonstrated the therapeutic values of the compounds. The risk benefit is, therefore, considered to be positive.

Beechams Chesty Cough Oral Solution

PL 00079/0663

STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application on 22nd September 2010
2	Following standard checks and communication with the applicant the MHRA considered the application is valid on 28th October 2010
3	Following assessment of the application the MHRA requested further information on 3rd November 2010, 10th February 2011 and 13th April 2011
4	The applicant responded to the MHRA's request, providing further information on 4th February 2011, 10th March 2011 and 14th April 2011
5	The application was determined on 17th May 2011

Beechams Chesty Cough Oral Solution

PL 00079/0663

STEPS TAKEN AFTER AUTHORISATION

Not applicable

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Beechams Chesty Cough Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Guaifenesin 100 mg, Glucose, liquid 3.0 g, Treacle 1.35 g

For full list of excipients, see section 6-1

3 PHARMACEUTICAL FORM
Oral solution

A dark, brown, viscous liquid with the odours of liquorice and aniseed.

4 CLINICAL PARTICULARS
4.1 Therapeutic indications
An expectorant for the symptomatic relief of coughs (including bronchial cough) and chesty catarrh, particularly associated with colds and flu.

The product also has a soothing, protective, demulcent action on a sore, irritated, tickling and inflamed throat.

4.2 Posology and method of administration
Adults and children over the age of 12: Take one 10ml dose (two 5ml spoonfuls) and repeat every 2 to 3 hours.

Route of Administration
Oral

4.3 Contraindications
Known hypersensitivity to guaifenesin, treacle or glucose or to any of the Excipients.

4.4 Special warnings and precautions for use
Patients suffering from chronic cough or asthma should consult a physician before taking this product.
Patients should stop using the product and consult a health care professional if cough lasts for more than 5 days or comes back, or is accompanied by a fever, rash or persistent headache.
Do not take with a cough suppressant.

Special Label Warnings
Keep out of the reach and sight of children.
If symptoms persist, consult your doctor.
Do not exceed the stated dose.
Do not use with other cough and cold medicines.

Contains 6.68 g total sugars per 10 ml dose. This should be taken into account in patients with diabetes mellitus.

Patients with rare glucose-galactose malabsorption should not take this medicine.

Contains 9.6 mg sodium per 10 ml dose. This should be taken into consideration in patients on a controlled sodium diet.

Contains sodium benzoate and sodium metabisulphite, which may rarely cause severe allergic reactions and bronchospasm.

4.5 Interaction with other medicinal products and other forms of interaction
None.

4.6 Pregnancy and lactation

Use in pregnancy and lactation is not contraindicated. However, as with all medicines, caution should be exercised during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Immune system disorders:
Unknown: allergic reactions, angioedema, anaphylactic reactions

Respiratory, thoracic and mediastinal disorders:
Unknown: Dyspnoea (in association with other symptoms of hypersensitivity)

Skin and subcutaneous disorders:
Unknown: Rash, urticaria

Gatrsointestinal disorders:
Unknown: nausea, vomiting, abdominal discomfort

4.9 Overdose

Very large doses of guaifenesin cause nausea and vomiting. Vomiting would be treated by fluid replacement and monitoring of electrolytes if indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Guaifenesin is an expectorant.
Treacle and liquid glucose are demulcents.

5.2 Pharmacokinetic properties

None Stated.

5.3 Preclinical safety data

There are no preclinical data of any relevance additional to that already included in other sections of the SmPC

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Deionised water, Macrogol 300, Glacial acetic acid, Sodium benzoate (E211), Capsicum tincture (contains ethanol), Sodium metabisulphite (E223), Aniseed oil, Xanthan gum, Levomenthol, Camphor, racemic, Sodium cyclamate, Acesulfame potassium, Liquorice aniseed flavour and Caramel colour (E150).

6.2 Incompatibilities

None.

6.3 Shelf life

Unopened: Three years.
Opened: Six months.

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

Amber cylindrical glass bottle fitted with a child resistant and tamper evident plastic screw cap.

Pack size: 100 or 160 ml

6.6 Special precautions for disposal
None.

7 MARKETING AUTHORISATION HOLDER
Beecham Group Plc
980 Great West Road
Brentford
Middlesex
TW8 9GS
United Kingdom

trading as: GlaxoSmithKline Consumer Healthcare, Brentford, TW8 9GS, U.K.

8 MARKETING AUTHORISATION NUMBER(S)
PL 00079/0663

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
17/05/2011

10 DATE OF REVISION OF THE TEXT
07/07/2011

PATIENT INFORMATION LEAFLET

Beechams®

Chesty Cough Oral Solution
Guaifenesin, Glucose liquid, Treacle

Please read right through this leaflet before you start using this medicine. This medicine is available without prescription, but you still need to use Chesty Cough Oral Solution carefully to get the best results from it.
- Keep this leaflet you may need to read it again.
- If you have any questions, or if there is anything you do not understand, ask your pharmacist.

In this leaflet:

1. What Beechams Chesty Cough Oral Solution does

This medicine is used for the short term relief of the symptoms of dry, tickly or scratchy coughs and sore throats. The medicine contains three active ingredients. Guaifenesin is an expectorant which loosens phlegm and relieves a chesty cough. Glucose liquid and treacle soothe and protect the surface of the mouth and throat to relieve their symptoms.

2. Check before you take this medicine

Do not take this medicine:

- **if you have ever had an allergic reaction** to guaifenesin, glucose liquid, treacle or to any of the other ingredients (listed in Section 6).
- if you are taking other **cough** or **cold medicines** or a **cough suppressant.**

Take special care with this medicine

- If you have **diabetes mellitus.** Each 10 ml dose contains **6.68 g total sugars.**

Ask your doctor before you take this medicine

- If you have a **chronic cough** or **asthma.**
- If you are on a **controlled-sodium diet.** Each 10 ml dose contains **9.6 mg of sodium.**
- If you have been told by your doctor that you have an intolerance to some sugars.

Pregnant and breast feeding

Talk to your doctor before taking this medicine if you are **pregnant** or **breastfeeding.**

3. How to take this medicine

Adults and children aged 12 years and over: **Take 10 ml (two teaspoonfuls) every 2 to 3 hours as needed.**

- **Do not give to children under 12 years.**
- **Do not take more frequently than every 2 hours.**
- **Do not not exceed the stated dose.**

If your symptoms persist, **see your doctor.**

4. Possible side effects

Like all medicines, Beechams Chesty Cough Oral Solution can have side effects, but not everybody gets them.

Stop taking the medicine and **seek immediate medical help** if you experience:
- Allergic reactions which may be severe such as skin rash and itching, sometimes with swelling of the mouth or face, shortness of breath or collapse.

These reactions are rare.

The following side effects may occur. **Stop** using this medicine and **consult** your doctor.
- Upset stomach, nausea or vomiting.
- If your cough lasts for more than 5 days or comes back, or is accompanied by a fever, rash or persistent headache.

If you do get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

5. How to store this medicine

Keep out of the reach and sight of children.
Do not use this medicine after the 'EXP' date shown on the pack.
Use within 6 months of opening.

6. Further information

Active ingredient Each 5 ml of medicine contains Guaifenesin 100 mg, Glucose liquid 3 g and Treacle 1.35 g.
Other ingredients Deionised water, Macrogol 300, Glacial acetic acid, Sodium benzoate (E211), Capsicum tincture (contains ethanol), Sodium metabisulphite (E223), Aniseed oil, Xanthan gum, Levomenthol, Camphor, racemic, Sodium cyclamate, Acesulfame potassium, Liquorice aniseed flavour and Caramel colour (E150).

Sodium benzoate (E 211) and sodium metabisulphite (E 223) may rarely cause severe allergic reactions and breathing difficulties.

Packs of Beechams Chesty Cough Oral Solution contain 100 ml or 160 ml.

The marketing authorisation holder is GlaxoSmithKline Consumer Healthcare, Brentford, TW8 9GS, U.K. and all enquiries should be sent to this address.

The manufacturer is Wrafton Laboratories Ltd, Wrafton, Braunton, North Devon, EX33 2DL, U.K.

This leaflet was last revised in April 2011

GlaxoSmithKline X000000/00

LABELLING


GSK Drawing No.: D302D001/04
Dimensions: 120 x 50 x 50 mm
Factory: Wrafton
Component: Carton
Date: 11th August 2009
Profile Keys:
Copy/Text Free
Pharma Code
15mm
DUMMY
Beechams CHESTY COUGH ORAL SOLUTION
Xoooooo/oo
oooooo
Beechams CHESTY COUGH ORAL SOLUTION
NON - DROWSY
100 ml
Please read the enclosed leaflet carefully before taking this medicine.
HOW TO TAKE
CONSULT YOUR DOCTOR
INGREDIENTS
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN
100 ml
Guaifenesin, Glucose liquid, Treacle
WHAT IS IT FOR?
The soothing formula of Beechams Chesty Cough Oral Solution helps clear your chesty cough.
Because it does not have any sedative effect, Beechams Chesty Cough Oral Solution allows you to get on with your normal working day without drowsiness.
Relief without drowsiness.
PL 00079/0208
DUMMY


GSK Drawing No.: D3020002/05
Dimensions: 135.5 x 58 x 58 mm
Factory: Perrigo
Component: Carton
Date: 22.10.2009
Profile Keys:
Varnish Free
Print Free
Copy/Text Free
Pharma Code
Quiet Zone
15mm
Beechams CHESTY COUGH ORAL SOLUTION
Beechams CHESTY COUGH ORAL SOLUTION
NON - DROWSY
160 ml
Please read the enclosed leaflet carefully before taking this medicine.
HOW TO TAKE
Adults and children 12 years and over:
Take 10 ml (two teaspoonfuls).
Repeat the dose every 2 to 3 hours as needed.
Use within 6 months of opening.
CONSULT YOUR DOCTOR
• If symptoms persist.
INGREDIENTS
Each 5 ml of syrup contains:
guaifenesin 100 mg, glucose liquid 3.0 g, treacle 1.35 g.
Also includes sodium benzoate (E 211) and sodium metabisulphite (E 223).
Total sugars content 6.68 g per 10 ml dose.
Sodium content 9.6 mg per 10 ml dose.
For professional advice on medicines consult your pharmacist.
KEEP OUT OF THE REACH AND SIGHT OF CHILDREN
GlaxoSmithKline
160 ml
GlaxoSmithKline Consumer Healthcare, Brentford, TW8 9GS, U.K.
Beechams CHESTY COUGH ORAL SOLUTION
Guaifenesin, Glucose liquid, Treacle
NON - DROWSY
160 ml
DUMMY
0 000000 000000
Beechams CHESTY COUGH ORAL SOLUTION
WHAT IS IT FOR?
The soothing formula of Beechams Chesty Cough Oral Solution helps clear your chesty cough.
This cough mixture contains a full strength expectorant making it effective for relief of chesty, bronchial cough's.
Beechams Chesty Cough Oral Solution loosens phlegm and catarrh and eases congestion. The demulcent action of Beechams Chesty Cough Oral Solution soothes and protects sore, irritated throats as well.
Because it does not have any sedative effect, Beechams Chesty Cough Oral Solution allows you to get on with your normal working day without drowsiness.
Relief without drowsiness.
PL 00079/0008
160 ml
GlaxoSmithKline
SCHAWK!
MHRA
REGULATORY
DATE


INGREDIENTS
Each 5 ml of syrup contains:
guaifenesin 100 mg, glucose liquid 3.0 g, treacle 1.35 g.
Also includes sodium benzoate (E 211) and sodium metabisulphite (E 223).
For professional advice on medicines consult your pharmacist.
Keep out of the reach and sight of children.
Total sugars content 6.68 g per 10 ml dose.
Sodium content 9.6 mg per 10 ml dose.
Use within 6 months of opening.
BN:
EXP:
GlaxoSmithKline
GlaxoSmithKline Consumer Healthcare,
Brentford, TW8 9GS, U.K.
PL 00079/0208 X000000/00
Beechams
CHESTY COUGH ORAL SOLUTION
Guaifenesin, Glucose liquid, Treacle
NON - DROWSY
100 ml
Please read the enclosed leaflet carefully before taking this medicine.
HOW TO TAKE
Adults and children 12 years and over:
Take 10 ml (two teaspoonfuls).
Repeat the dose every 2 to 3 hours as needed.
CONSULT YOUR DOCTOR
• if symptoms persist.
DUMMY


INGREDIENTS
Each 5 ml of syrup contains:
guaifenesin 100 mg, glucose liquid 3.0 g, treacle 1.35 g.
Also includes sodium benzoate (E 211) and sodium metabisulphite (E 223).
For professional advice on medicines consult your pharmacist.
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BN:
EXP:
GlaxoSmithKline
GlaxoSmithKline Consumer Healthcare,
Brentford, TW8 9GS, U.K. PL 00079/0208 X000000/00
Beechams
CHESTY COUGH ORAL SOLUTION
Guaifenesin, Glucose liquid, Treacle
NON - DROWSY
160 ml
Please read the enclosed leaflet carefully before taking this medicine.
HOW TO TAKE
Adults and children 12 years and over:
Take 10 ml (two teaspoonfuls).
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CONSULT YOUR DOCTOR
• if symptoms persist.
DUMMY