BENYLIN CHILDREN'S CHESTY COUGHS SACHETS (GUAIFENESIN 50MG/5ML SYRUP)

PL 15513/0139

UKPAR

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BENYLIN CHILDREN'S CHESTY COUGHS SACHETS (GUAIFENESIN 50MG/5ML SYRUP)

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LAY SUMMARY

The MHRA granted Pfizer Consumer Healthcare a Marketing Authorisation (licence) for the medicinal product BENYLIN Children's Chesty Coughs Sachets (PL 15513/0139) on 3rd April 2006. This General Sales List (GSL) medicine is used for the symptomatic relief of productive coughs in children.

BENYLIN Children's Chesty Coughs Sachets contain the active ingredient guaifenesin which is an expectorant used to loosen mucus in the lungs and make it easier to cough up.

This application is a duplicate of a previously granted application for BENYLIN Children's Chesty Coughs Syrup (PL 15513/0052) held by Pfizer Consumer Healthcare.

No new or unexpected safety concerns arose from this simple application. It was, therefore, judged that the benefits of taking BENYLIN Children's Chesty Coughs Sachets outweigh the risks. Hence a Marketing Authorisation has been granted.

BENYLIN CHILDREN'S CHESTY COUGHS SACHETS (GUAIFENESIN 50MG/5ML SYRUP)

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SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product BENYLIN Children's Chesty Cough Sachets (PL 15513/0139) to Pfizer Consumer Healthcare on 3rd April 2006. This medicinal product is available as General Sales List (GSL).

The application was submitted according to article 10.c [formerly article 10.1(a)(i) of Directive 2001/83/EC], cross-referring to BENYLIN Children's Chesty Coughs Syrup (PL 15513/0052), which was granted a marketing authorisation on 16th June 1997. This authorisation was itself a Change of Ownership from PL 00018/0232 granted on 16th July 1996.

No new data was submitted nor was it necessary for this simple application, as the data is 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 public assessment report was generated for it.

The product contains the active ingredient guaifenesin, which is an expectorant, thought to stimulate receptors in the gastric mucosa, in order to increase volume and decrease viscosity of mucus to make it easier to cough up. BENYLIN Children's Chesty Coughs Sachets is indicated for the symptomatic relief of productive coughs which benefit from the administration of an expectorant.

PHARMACEUTICAL ASSESSMENT

INTRODUCTION

This is an abridged application made under Article 10.c [formerly article 10.1(a)(i) of EC Directive 2001/83] and is considered to be an essentially similar product to that of PL 15513/0052 (Benylin Children's Chesty Coughs). The licence is held by Pfizer Consumer Healthcare granted 16th June 1997. PL 15513/0052 is a change of ownership of PL 00018/0232 held by Parke Davis & Co granted 16th July 1996.

A letter of consent has been supplied by Pfizer Consumer Healthcare for cross-reference to PL 15513/0052 in conjunction with this application.
Relevant quality inspection certification has been provided for the finished product manufacturer from the French Authorities dated May 2004.

EXPERT REPORTS

Satisfactory statements provided.

PRODUCT LITERATURE

1. SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

The SPC supplied is satisfactory and consistent with the cross-reference product.

2. LABELLING

The labelling supplied is satisfactory and consistent with the cross-reference product.

3. PATIENT INFORMATION LEAFLET (PIL)

The PIL supplied is satisfactory and consistent with the cross-reference product.

4. MARKETING AUTHORISATION APPLICATION (MAA)

The MAA form is satisfactory and consistent with the cross-reference product.

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

As this is a duplicate application for PL 15513/0052, no new clinical data have been supplied and none are required.

OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY

The data for this application is consistent with that previously assessed for the cross-reference product and as such has been judged to be satisfactory.

PRECLINICAL

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

EFFICACY

Guaifenesin is a well known drug and has been used to treat the symptoms of productive coughs for many years. The data supplied with this application is identical to the previously approved marketing authorisation for BENYLIN Children's Coughs Syrup.

No new or unexpected safety concerns arise from this application.

The SPC, PIL and labelling are satisfactory and consistent with that for the cross-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 cross-reference product. Extensive clinical experience with guaifenesin is considered to have demonstrated the therapeutic value of the product. The risk benefit is therefore considered to be positive.

BENYLIN CHILDREN'S CHESTY COUGHS SACHETS (GUAIFENESIN 50MG/5ML SYRUP)

PL 15513/0139

STEPS TAKEN FOR ASSESSMENT

1	The MHRA received the marketing authorisation application on 09/12/2004.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 12/01/2005.
3	Following assessment of the application the MHRA requested further information on 08/02/2005, 03/06/2005, 07/12/2005.
4	The applicant responded to the MHRA's requests, providing further information on 25/04/2005, 31/07/2005 and 24/01/2006.
5	The application was determined on 03/04/2006

BENYLIN CHILDREN'S CHESTY COUGHS SACHETS (GUAIFENESIN 50MG/5ML SYRUP)

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STEPS TAKEN AFTER ASSESSMENT

Date submitted	Application type	Scope	Outcome

BENYLIN CHILDREN'S CHESTY COUGHS SACHETS (GUAIFENESIN 50MG/5ML SYRUP)

PL 15513/0139

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

BENYLIN Children's Chesty Coughs Sachets, 50 mg/ 5ml syrup

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

BENYLIN Children's Chesty Coughs Sachets contains 50 mg guaifenesin in each 5 ml.

For excipients, see 6.1

3. PHARMACEUTICAL FORM

Syrup
A clear, colourless syrup

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

BENYLIN Children's Chesty Coughs Sachets is indicated for the symptomatic relief of productive coughs which benefit from the administration of an expectorant.

4.2. Posology and method of administration

For oral use

Adults and children over 12 years:
Not applicable.

Children aged 6 to 12 years:
10 ml syrup four times daily.
Maximum daily dose: 40 ml syrup (400 mg guaifenesin)

Children aged 1 to 5 years:
5 ml syrup four times daily.
Maximum daily dose: 20 ml syrup (200 mg guaifenesin)

Children under 1 year:
BENYLIN Children's Chesty Coughs Sachets is not recommended for administration to children under 1 year of age, except on the advice of a physician.

The Elderly
Not applicable.

4.3. Contraindications

BENYLIN Children's Chesty Coughs Sachets is contraindicated in individuals with known hypersensitivity to the product, or any of its components.

4.4. Special warnings and precautions for use

BENYLIN Children's Chesty Coughs Sachets should be not used for persistent or chronic cough, such as occurs with asthma, or where cough is accompanied by excessive secretions, unless directed by a physician.

Caution should be exercised in the presence of severe renal or severe hepatic impairment.

Patients with rare hereditary problems of fructose intolerance should not take this medicine’

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

If urine is collected within 24 hours of a dose of BENYLIN Children's Chesty Coughs Sachets a metabolite of guaifenesin may cause a colour interference with laboratory determinations of urinary 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

4.6. Pregnancy and lactation

This product has been formulated specifically for children, and would therefore not normally be taken during pregnancy and lactation.

Insufficient information is available on the effects of BENYLIN Children's Chesty Coughs Sachets during human pregnancy. BENYLIN Children's Chesty Coughs Sachets, like most medicines, should not be used during pregnancy unless the potential benefit of treatment to the mother outweighs the possible risks to the developing foetus.

Guaifenesin is excreted in breast milk in small amounts with no effect expected on the infant.

4.7. Effects on ability to drive and use machines

Not applicable

4.8. Undesirable effects

Side effects resulting from guaifenesin administration are very rare.

4.9. Overdose

Symptoms and signs
The effects of acute toxicity from guaifenesin may include gastro-intestinal discomfort, nausea and drowsiness.

Treatment
Treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Guaifenesin is thought to exert its pharmacological action by stimulating receptors in the gastric mucosa. This increases the output from secretory glands of the gastrointestinal system and reflexly increases the flow of fluids from glands lining the respiratory tract. The result is an increase in volume and decrease in viscosity of bronchial secretions. Other actions may include stimulating vagal nerve endings in bronchial secretory glands and stimulating certain centres in the brain, which in turn enhance respiratory fluid flow. Guaifenesin produces its expectorant action within 24 hours.

5.2. Pharmacokinetic properties

Absorption
Guaifenesin is well absorbed from the gastro-intestinal tract following oral administration, although limited information regarding its pharmacokinetics is available. After the administration of 600 mg guaifenesin to healthy adult volunteers, the C_{max} was approximately 1.4 ug/ml, with t_{max} occurring approximately 15 minutes after drug administration.

Distribution
No information is available on the distribution of guaifenesin in humans.

Metabolism and elimination
Guaifenesin appears to undergo both oxidation and demethylation. Following an oral dose of 600 mg guaifenesin to 3 healthy male volunteers, the t½ was approximately 1 hour and the drug was not detectable in the blood after approximately 8 hours.

Pharmacokinetics in Renal/Hepatic Impairment
There have been no specific studies of BENYLIN Children's Chesty Coughs Sachets or guaifenesin in subjects with renal or hepatic impairment.
Caution is therefore recommended when administering this product to subjects with severe renal or hepatic impairment.

Pharmacokinetics in the Elderly
Not applicable.

5.3. Preclinical safety data

Mutagenicity
There is insufficient information available to determine whether guaifenesin has mutagenic potential.

Carcinogenicity
There is insufficient information available to determine whether guaifenesin has carcinogenic potential.

Teratogenicity
There is insufficient information available to determine whether guaifenesin has teratogenic potential.

Fertility
There is insufficient information available to determine whether guaifenesin has the potential to impair fertility.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Glycerol
Sorbitol liquid(non-crystallising) (E420)
Sodium citrate
Citric acid monohydrate
Sodium saccharin
Sodium benzoate (E211)
Carmellose Sodium
Strawberry 580.193/T
Purified water

6.2. Incompatibilities

None known

6.3. Shelf life

2 years (sachets)

6.4. Special precautions for storage

Do not store above 25°C.

6.5. Nature and contents of container

BENYLIN Children's Chesty Coughs Sachets is stored in 10 x 5ml aluminium foil laminate sachets

A spoon with a 5ml measure is supplied with the sachet pack.

6.6 Special precautions for disposal

None applicable.

7. MARKETING AUTHORISATION HOLDER

Pfizer Consumer Healthcare

Alternative Trading Style:
Warner-Lambert Consumer Healthcare
Walton Oaks
Dorking Road
Walton-on-the-Hill
Surrey KT20 7NS
United Kingdom

8. MARKETING AUTHORISATION NUMBER

PL 15513/0139

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

03/04/2006

10 DATE OF REVISION OF THE TEXT

BENYLIN CHILDREN'S CHESTY COUGHS SACHETS (GUAIFENESIN 50MG/5ML SYRUP)

PL 15513/0139

PRODUCT INFORMATION LEAFLET

Benylin®

CHILDREN'S Chesty Coughs Sachets

Guaifenesin 50 mg/5 ml Syrup

1-12 YEARS

Read all of this leaflet carefully because it contains important information for your child. This medicine is available without prescription for you to treat a mild illness without a doctor's help. Nevertheless, you still need to use this product carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- Go and see the doctor if your child's symptoms worsen or do not improve after a few days.

Benylin Children's Chesty Coughs Sachets 50 mg/5 ml Syrup

This product is a clear, colourless syrup. It contains 50 mg of the active ingredient Guaifenesin in each 5 ml. It also contains glycerol, sorbitol liquid (E420), carmellose sodium, sodium citrate, sodium saccharin, sodium benzoate (E211), citric acid monohydrate, strawberry flavour and water.

Marketing Authorisation holder: Pfizer Consumer Healthcare, Walton-on-the-Hill, Surrey, KT20 7NS.

Manufacturer: Pfizer PGM, 5 avenue de Concyr, 45071 Orleans, Cedex 2, France.

What this product is and what it is used for

It contains Guaifenesin, an expectorant to help loosen mucus (phlegm) from the lungs and makes it easier to cough up.
This product is used for the symptomatic relief of children's productive cough.

This product is available in 10 x 5 ml sachets.

Before you give your child this product

Do not give your child this product if:

- He or she has ever had a bad reaction to the product or any of the ingredients.
- Your child is under 1 year.

Take special care with this product if:

- Your child has ever had a persistent cough such as occurs with asthma, or produces a lot of mucus (phlegm).
- If your child has ever had kidney or liver problems.

Please consult your doctor even if the statements were applicable to your child at any time in the past.

If an older child or adult is taking the medicine they should consult their doctor or pharmacist if they are pregnant or breast-feeding.

Important information about some of the ingredients in this product

Each 5 ml of product contains 1.78 g of sorbitol, which may have a mild laxative effect. Calorific value 2.6 kcal/g sorbitol. If you have an intolerance to some sugars, contact your doctor before taking this product.

Sodium content 14.88 mg/5 ml. To be taken into consideration by patients on a controlled sodium diet.

How to give this product

There is a single ended 5 ml spoon in the pack.

For oral use:
Check the table below to see how much to give. Do not give two doses at the same time.

Age	Dosage
Children aged 6 to 12 years.	Give two 5 ml spoonfuls (sachets) four times a day. Do not give more than eight 5 ml spoonfuls (sachets) in 24 hours.
Children aged 1 to 5 years.	Give one 5 ml spoonful (sachet) four times a day. Do not give more than four 5 ml spoonfuls (sachets) in 24 hours.
Children under 1 year old.	Not suitable.

If anyone takes more than they should, talk to a doctor or pharmacist immediately.

Possible side-effects

Side-effects are not common with this product, and when they do occur they are usually mild.
If you notice any side-effects please tell your doctor or pharmacist.

Storing this product

Keep this product out of the reach and sight of children.
Do not store above 25°C.
Do not use after the expiry date on the label.

This leaflet was revised August 2005.

Pfizer Consumer Healthcare

121-200701

BENYLIN CHILDREN'S CHESTY COUGHS SACHETS
(GUAIFENESIN 50MG/5ML SYRUP)

PL 15513/0139

CARTON

SACHET


TEAR OR CUT HERE
5 ml Sachet
Benylin®
CHILDREN'S
Chesty Coughs
Sachets
Guaifenesin 50 mg/5 ml Syrup
1-12 YEARS
Non-Drowsy
Sugar & Colour-free
Strawberry Flavour
121-200700
DOSE: For oral use only.
Children 1 to 5 years - One 5 ml spoonful 4 times a day.
Children 6 to 12 years - Two 5 ml spoonfuls 4 times a day.
Do not use more than 4 doses in 24 hours.
Not suitable for children under 1 year.
Diabetics - This product contains sorbitol (carbohydrate content approx. 1.78 g per 5 ml). Calorific value 2.6 kcal/g sorbitol.
Advice for older children and adults - As with all similar medicines, if you are pregnant or breast-feeding, consult your doctor or pharmacist before taking this medicine. Please consult your doctor or pharmacist if symptoms persist.
CONTENTS Each 5 ml of cough syrup contains: Guaifenesin 50 mg.
Other ingredients include: Sorbitol liquid (E420).
Sodium content: 14.88 mg/5 ml.
The sugar substitute in this product will not cause dental decay.
Please read the enclosed leaflet carefully before use.
Do not store above 25 °C.
Keep out of the reach and sight of children.
WARNING: DO NOT EXCEED STATED DOSE
Marketing Authorisation holder:
Pfizer Consumer Healthcare, Walton-on-the-Hill, Surrey, KT20 7NS.
PL 15513/0139.
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Pfizer Consumer Healthcare
BN/EXP TO BE STAMPED HERE.