English Herbal Medicines Horehound Plus Cough Syrup

Brooke Green Horehound Plus Cough Mixture

Napiers Cough Soother Herbal Syrup

THR 28255/0022

UKPAR

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The Medicines and Healthcare products Regulatory Agency (MHRA) granted Rutland Biodynamics Ltd a Traditional Herbal Registration Certificate for the traditional herbal medicinal products English Herbal Medicines Horehound Plus Cough Syrup, Brooke Green Horehound Plus Cough Mixture and Napiers Cough Soother Herbal Syrup (Traditional Herbal Registration number: THR 28255/0022). These products are identical to each other apart from in product name and will be collectively referred to as Rutland Cough Syrup in the remainder of this report. Rutland Cough Syrup is available without prescription and can be bought from pharmacies and other outlets.

Rutland Cough Syrup is a traditional herbal medicinal product used for the symptomatic relief of coughs, based on traditional use only. The active ingredients in this product come from the roots of the Pleurisy (*Asclepias tuberosa* L.) Elecampane (*Inula helenium* L.) and Skunk cabbage (*Symlocarpus foetidus* (L.) Salisb.) plants, White Horehound (*Marrubium vulgare* L.) leaves and flowering tops and Lobelia (*Lobelia inflata* L.) herb.

This registration is based exclusively upon evidence of the use of Pleurisy, Elecampane, Skunk cabbage, White Horehound and Lobelia as traditional herbal medicines and not upon data generated from clinical trials. There is no requirement under the Traditional Herbal Registration scheme to prove scientifically that the product works.

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Traditional Herbal Registration certificate could be granted.
ENGLISH HERBAL MEDICINES HOREHOUND PLUS COUGH SYRUP
BROOKE GREEN HOREHOUND PLUS COUGH MIXTURE
NAPIERS COUGH SOOTHER HERBAL SYRUP

THR 28255/0022

SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicine Rutland Cough Syrup (THR 28255/0022) to Rutland Biodynamics Ltd on 17 October 2011. This product is on the general sales list (GSL).

A product licence of right (PLR) was granted for this product, which was reviewed, and a Marketing Authorisation (product licence) was granted to Potters Limited (PL 00250/5096R) on 7 August 1990 (under the product name Potter's Horehound and Aniseed Cough Mixture). Following a change of ownership on 3 February 2009, the product licence was transferred to Rutland Biodynamics Ltd under product licence number PL 28255/0013. Confirmation is given that PL 28255/0013 will be cancelled after the THR is granted.

This THR application was made under Article 16.c of Directive 2001/83 EC in accordance with arrangements to transfer certain herbal products with a marketing authorisation (product licence) to a THR (according to MHRA Guidance dated January 2009). The application falls within the simplified THR application Category A as no changes have been made to the formulation of the product. No new data were submitted, nor was it necessary for this application, as the data are essentially identical to those of the existing product.
PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE:  PLEURISY ROOT

Scientific name of the plant:  Asclepias tuberosa L.
Plant family:  Asclepiadaceae

The herbal substance specification is in line with that applied to the herbal substance used in the already licensed product. It is, therefore, acceptable.

HERBAL PREPARATION:  PLEURISY ROOT LIQUID EXTRACT

Ratio of the herbal substance to the herbal preparation (native):  1:1
Extraction solvent:  Ethanol 35 % (v/v)

The herbal preparation specification is in line with that applied to the herbal preparation used in the already licensed product. It is, therefore, acceptable.

HERBAL SUBSTANCE:  ELECAMPANE ROOT

Scientific name of the plant:  Inula helenium L.
Plant family:  Compositae

The herbal substance specification is in line with that applied to the herbal substance used in the already licensed product. It is, therefore, acceptable.

HERBAL PREPARATION:  ELECAMPANE ROOT LIQUID EXTRACT

Ratio of the herbal substance to the herbal preparation (native):  1:1
Extraction solvent:  Ethanol 21 % (v/v)

The herbal preparation specification is in line with that applied to the herbal preparation used in the already licensed product. It is, therefore, acceptable.

HERBAL SUBSTANCE:  WHITE HOREHOUND LEAVES AND FLOWERING TOPS

Scientific name of the plant:  Marrubium vulgare L.
Family:  Lamiaceae
The herbal substance specification is in line with that applied to the herbal substance used in the already licensed product. It is, therefore, acceptable.

**HERBAL PREPARATION:**  
**WHITE HOREHOUND LEAVES AND FLOWERING TOPS LIQUID EXTRACT**

**Ratio of the herbal substance to the herbal preparation (native):**  
1:1

**Extraction solvent:**  
Ethanol 20 % (v/v)

The herbal preparation specification is in line with that applied to the herbal preparation used in the already licensed product. It is, therefore, acceptable.

**HERBAL SUBSTANCE:**  
**SKUNK CABBAGE ROOT**

**Scientific name of the plant:**  
*Symlocarpus foetidus* (L.) Salisb

**Family:**  
Araceae

The herbal substance specification is in line with that applied to the herbal substance used in the already licensed product. It is, therefore, acceptable.

**HERBAL PREPARATION:**  
**SKUNK CABBAGE ROOT LIQUID EXTRACT**

**Ratio of the herbal substance to the herbal preparation (native):**  
1:1

**Extraction solvent:**  
Ethanol 21 % (v/v)

The herbal preparation specification is in line with that applied to the herbal preparation used in the already licensed product. It is, therefore, acceptable.

**HERBAL SUBSTANCE:**  
**LOBELIA HERB**

**Scientific name of the plant:**  
*Lobelia inflata* L.

**Family:**  
Campanulaceae

The herbal substance specification is in line with that applied to the herbal substance used in the already licensed product. It is, therefore, acceptable.

**HERBAL PREPARATION:**  
**LOBELIA HERB TINCTURE**

**Ratio of the herbal substance to the herbal preparation (native):**  
1:12
Extraction solvent: Ethanol 50 % (v/v)

The herbal preparation specification is in line with that applied to the herbal preparation used in the already licensed product. It is, therefore, acceptable.

HERBAL PRODUCT: RUTLAND COUGH SYRUP

Description and Composition of the Herbal Product
Rutland Cough Syrup is a dark reddish-brown, slightly viscous, oral liquid. Each 5 ml of oral liquid contains 75 microlitres of liquid extract from dried Pleurisy root, 75 microlitres of liquid extract from dried Elecampane root, 75 microlitres of liquid extract from dried White Horehound leaves and flowering tops, 75 microlitres of liquid extract from dried Skunk cabbage root and 112.5 microlitres of tincture from dried Lobelia herb. The product also contains the excipients wild cherry liquid extract, alcohol (90%), star anise oil, capsicum tincture, caramel, glycerol, sucrose and water. The formulation is essentially identical to that of the already licensed product. It is, therefore, acceptable.

Manufacture
The manufacturing process is in line with that of the already licensed product and is satisfactory.

Finished Product Specification
The finished product specification is in line with that of the already licensed product and is satisfactory.

Container Closure System
The product is packed in 100ml or 200ml glass bottles with a bakelite screwcap. This type of packaging has been used to store the already licensed product and is satisfactory.

Stability
The product shelf-life of 3 years was applied to the already licensed product and is appropriate.

Summary of Product Characteristics, labels and Patient Information Leaflets
All product literature is in line with that of the already licensed product.

A product leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet/labelling is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

ASSESSOR'S OVERALL CONCLUSIONS
It is recommended that a Traditional Herbal Registration can be granted.
PRECLINICAL ASSESSMENT

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

Assurance has been given that the results of genotoxicity testing will be provided by the renewal date of the THR.

PRODUCT LITERATURE
All product literature is satisfactory from a preclinical point of view.

ASSessor's OVERALL CONCLUSIONS
It is recommended that a Traditional Herbal Registration can be granted.
CLINICAL ASSESSMENT

INTRODUCTION
The clinical particulars for Rutland Cough Syrup are identical to those for the already licensed product. This is satisfactory.

PRODUCT LITERATURE
All product literature is medically satisfactory.

ASSESSOR'S OVERALL CONCLUSIONS
It is recommended that a Traditional Herbal Registration can be granted.
OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY
Rutland Cough Syrup is identical to an already licensed product. It is, therefore, pharmaceutically satisfactory.

PRECLINICAL
No new preclinical data were submitted and none are required for an application of this type. The results of genotoxicity testing will be provided before the THR is renewed.

EFFICACY
No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products (THMP).

SAFETY
No new or unexpected safety concerns arose from this application.

RISK ASSESSMENT
The quality of the product is acceptable and no new preclinical or clinical safety concerns have been identified. The risk: benefit balance is acceptable and a Traditional Herbal Registration may be granted.
ENGLISH HERBAL MEDICINES HOREHOUND PLUS COUGH SYRUP
BROOKE GREEN HOREHOUND PLUS COUGH MIXTURE
NAPIERS COUGH SOOTHER HERBAL SYRUP

THR 28255/0022

**STEPS TAKEN FOR ASSESSMENT**

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The MHRA received the Traditional Herbal Registration application on 22 September 2010.</td>
</tr>
<tr>
<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 4 October 2010.</td>
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<tr>
<td>3</td>
<td>Following assessment of the application the MHRA requested further information relating to the quality dossier on 11 April 2011.</td>
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<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on the quality dossier on 8 June 2011.</td>
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<td>5</td>
<td>Following assessment of the response the MHRA requested further information relating to the quality dossier on 20 June 2011.</td>
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<tr>
<td>6</td>
<td>The applicant responded to the MHRA’s requests, providing further information on the quality dossier on 24 August 2011.</td>
</tr>
<tr>
<td>7</td>
<td>Following assessment of the response the MHRA requested further information relating to the quality dossier on 6 September 2011.</td>
</tr>
<tr>
<td>8</td>
<td>The applicant responded to the MHRA’s requests, providing further information on the quality dossier on 7 October 2011.</td>
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<tr>
<td>9</td>
<td>A THR was granted on 17 October 2011.</td>
</tr>
</tbody>
</table>
1 NAME OF THE MEDICINAL PRODUCT
English Herbal Medicines Horehound Plus Cough Syrup
Brooke Green Horehound Plus Cough Mixture
Napiers Cough Soother Herbal Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 5ml of oral liquid contains:-

75 microlitres of liquid extract from dried Pleurisy root* (*Asclepias tuberosa L.) (1:1).
Extraction solvent: ethanol 35% v/v.
75 microlitres of liquid extract from dried Elecampane root * (*Inula helenium L.) (1:1).
Extraction solvent: ethanol 21% v/v.
75 microlitres of liquid extract from dried White Horehound leaves and flowering tops* (*Marrubium vulgare L.) (1:1). Extraction solvent: ethanol 20% v/v.
75 microlitres of liquid extract from dried Skunk cabbage root (*Symplocarpus foetidus L.) Salisb.) (1:1).
Extraction solvent: ethanol 21% v/v.
112.5 microlitres of Tincture Lobelia Acid from dried Lobelia herb* (*Lobelia inflata L.) (1:12).
Extraction solvent: ethanol 50% v/v. Also contains 5.8% acetic acid.

* Organically produced herbal ingredient.

Each 5ml of oral liquid also contains approximately:

158 mg Ethanol (alcohol) equivalent to 4 ml of beer or 1.7 ml of wine – 4% (v/v).
2.77g Sucrose

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM
Oral liquid.
Dark reddish-brown slightly viscous liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
A traditional herbal medicinal product used for the symptomatic relief of coughs, based on traditional use only.
4.2 **Posology and method of administration**
For oral use only.

*Adults and the Elderly*
Take two 5ml spoonfuls three times a day.

*Children over 12:*
Take one 5ml spoonful three times a day.

The use is not recommended in children under 12 years of age (see 4.4. Special warnings and precautions for use).

If symptoms worsen or persist after 7 days, a doctor or qualified healthcare practitioner should be consulted.

4.3 **Contraindications**
Patients with known hypersensitivity to any of the active ingredients, any of the excipients or to plants of the Asteraceae (Compositae) family.

4.4 **Special warnings and precautions for use**
Do not exceed the stated dose.
Contains alcohol – up to 316 mg ethanol per 10ml dose (equivalent to 8 ml of beer or 3.5 ml of wine).
Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high risk groups such as patients with liver disease, or epilepsy.

Contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.

If dyspnoea, fever or purulent sputum occurs, a doctor of qualified healthcare practitioner should be consulted.

If symptoms worsen or persist after 7 days, a doctor or qualified healthcare practitioner should be consulted.

The use is not recommended in children under 12 years of age because no data on safety are available.

4.5 **Interaction with other medicinal products and other forms of interaction**
No studies have been carried out to determine if drug interactions occur with this product.

Contains alcohol, and should therefore be avoided in patients taking other medication known to interact with alcohol (e.g. Metronidazole).
4.6 **Fertility, pregnancy and lactation**
The safety of the product during pregnancy and lactation has not been established, therefore the use of this product during pregnancy and lactation is not recommended.

4.7 **Effects on ability to drive and use machines**
No studies on the effect of this product on the ability to drive or use machinery have been performed.
This product contains alcohol (see Section 2).

4.8 **Undesirable effects**
Allergic reactions, including contact dermatitis may occur after ingesting Elecampane, White Horehound and Skunk Cabbage and Pleurisy root. The frequency is not known.

Lobelia can cause nausea, vomiting, diarrhoea, tremors and dizziness. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or qualified healthcare practitioner should be consulted.

4.9 **Overdose**
No case of overdose has been reported.
Overdose of Lobelia could produce nausea, vomiting or diarrhoea, profuse diaphoresis, paresis, hypotension and coma. High doses could be cardioactive. If symptoms arise, treatment should be supportive.

Large doses of Elecampane may cause vomiting, diarrhoea, spasms and symptoms of paralysis.

Overdose of Pleurisy root may cause diarrhoea and vomiting.

Overdose of this product may result in alcohol intoxication: the amount in a full bottle (3.2g in 100ml or 6.3 g in 200 ml: equivalent to 0.2 or 0.4 large glasses of wine respectively) may result in intoxication and should be treated accordingly.

Symptomatic and supportive measures should be taken as appropriate.

5 **PHARMACOLOGICAL PROPERTIES**

5.1 **Pharmacodynamic properties**
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2 **Pharmacokinetic properties**
Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.
5.3 Preclinical safety data
Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Wild Cherry Liquid Extract
Alcohol (90%)
Star anise Oil
Capsicum Tincture
Caramel
Glycerol
Sucrose
Water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
Three years.

6.4 Special precautions for storage
This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container
Glass bottle with bakelite screwcap: 100ml and 200ml.

6.6 Special precautions for disposal
No special requirements.

7 MARKETING AUTHORISATION HOLDER
Rutland Biodynamics Ltd, Town Park Farm, Brooke, Rutland, LE15 8DG.

8 MARKETING AUTHORISATION NUMBER(S)
THR 28255/0022

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
17/10/2011

10 DATE OF REVISION OF THE TEXT
17/10/2011
English Herbal Medicines Horehound Plus Cough Syrup:

Product Description:
Horehound Plus Cough Syrup is a traditional herbal medicinal product used for the symptomatic relief of coughs based on traditional use only.

Ingredients:
- Water
- Horehound (Artemisia absinthium L. [Labiatae])
- Honey
- Ethanol
- Wild Cherry (Prunus avium L. [Rosaceae])
- Benzyl Alcohol

Possible Side Effects:
- Like all medicines, this product can have side effects, although not everybody gets them.
- These include:
  - Uncommon side-effects:
    - Allergic reactions including contact dermatitis
    - Digestive upsets (nausea, vomiting or diarrhoea)
    - Headache and dizziness

If these persist or become troublesome stop taking the product. Stop taking this product immediately if you experience any allergic skin reaction.
Tell your doctor if you notice any other side effects.

Storing this Product:
Do not use after the expiry date shown on the bottle. Return any out of date medicine to your pharmacist who will dispose of it for you.
This product does not require any special storage conditions. Keep the bottle tightly closed.

Further Information:
If you take too much of this product (overdose)
If you take more than the recommended dose, speak to a doctor, pharmacist or healthcare practitioner and take this booklet with you.

If you forget to take this product
Continue to take your usual dose at the usual time. It does not matter if you have missed a dose.

You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Alternatively, you can get a paper Yellow Card form from your GP's surgery or pharmacy, or call 0800 228 758

This product is available in packets of 100ml and 200ml. Not all pack sizes may be marketed.

It is advisable to read this leaflet before taking the product.

Manufacturer and Traditional Herbal Registration Holder: Rutland Biocamica Ltd, Bank Park Lane, Brooke, Rutland LE15 8BD

THR No: 28255/0022
Label last revised in September 2011.
Brooke Green Horehound Plus Cough Mixture:

Patient Information Leaflet
Brooke Green Horehound Plus Cough Mixture
Pleurisy root, Elecampane root, White Horehound leaves and flowering tops, Skunk cabbage root and Lobelia herb extract

Please read this leaflet carefully before using Brooke Green Horehound Plus Cough Mixture. It contains important information about this medicine.
Keep this leaflet. You may want to read it again. If you need more information or advice, please ask your doctor, pharmacist or qualified healthcare practitioner.

What is in this leaflet
1. What this product is and what it is used for
2. Before you take this product
3. How to take this product
4. Possible side effects
5. How to store this product
6. Further information

What this product is and what it is used for
Brooke Green Horehound Plus Cough Mixture is a traditional herbal medicinal product used for the symptomatic relief of coughs, based on traditional use only.

Before you take this product
Do not take this product if you:
- are under 12 years old
- are pregnant or breastfeeding
- are allergic to any of the ingredients or to plants of the Asteraceae (Compositae) family such as daisies, marigolds or artichokes (see section 6)

You should also know:
This product contains approx. 4 % (v/v) ethanol (alcohol) approximately 316 mg ethanol (alcohol) per dose equivalent to 8 ml of beer or 3.5 ml of wine. Harmful for people suffering from alcoholism or liver-disease.

This product contains sucrose. If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.

How to take this product
For oral use only.
Adults and the Elderly: Take two 5ml spoonfuls three times a day.
Children over 12: Take one 5ml spoonful three times a day.
Do not exceed the stated dose. This formulation is not suitable for children under 12.

If your symptoms persist after 7 days or worsen, or you have shortness of breath, fever or green mucus (phlegm), or side effects not mentioned in the leaflet occur, speak to your doctor, pharmacist or qualified healthcare practitioner.

If you take too much of this product (overdose)
If you take more than the recommended dose, speak to a doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you. Overdose of this product may result in alcohol intoxication and should be treated accordingly (see Section 2 – You should also know).
If you forget to take this product
Continue to take your usual dose at the usual time. It does not matter if you have missed a dose.

4. Possible side effects
Like all medicines, this product can have side effects, although not everybody gets them. These include:

Uncommon side-effects
- allergic reactions including contact dermatitis
- digestive upsets (nausea, vomiting or diarrhoea)
- tremors and dizziness

If these persist or become troublesome stop taking the product. Stop taking this product immediately if you experience any allergic skin reaction.

5. How to store this product
Do not use after the expiry date shown on the bottle
Return any out of date medicine to your pharmacist who will dispose of it for you.
This product does not require any special storage conditions. Keep the bottle tightly closed.

6. Further information
Brooke Green Horehound Plus Cough Mixture is a dark reddish-brown slightly viscous liquid.

Ingredients: Each 5ml of oral liquid contains:
75 microlitres of liquid extract from dried Pleurisy root* (Asclepias tuberosa L.) (1:1).
Extraction solvent: ethanol 35% v/v.
75 microlitres of liquid extract from dried Elecampane root* (Inula helenium L.) (1:1).
Extraction solvent: ethanol 21% v/v.
75 microlitres of liquid extract from dried White Horehound leaves and flowering tops* (Marribium vulgare L.) (1:1). Extraction solvent: ethanol 20% v/v.
75 microlitres of liquid extract from dried Skunk cabbage root (Symlocarpus foetidus (L.) Salisb.) (1:1). Extraction solvent: ethanol 21% v/v.
112.5 microlitres of Tincture Lobelia Acid from dried Lobelia herb* (Lobelia inflata L.) (1:12).
Extraction solvent: ethanol 50% v/v. Also contains 5.8% acetic acid.

* Certified organically produced herbal ingredients.

This product also contains the following ingredients: Wild Cherry Liquid Extract, Alcohol (90%),
Star anise Oil, Capsicum Tincture, Caramel, Glycerol, Sucrose, Water
This product is available in packs of 100 ml and 200ml. Not all pack sizes may be marketed.

Manufacturer and Traditional Herbal Registration Holder:
Rutland Biodynamics Ltd., Town Park Farm, Brooke, Rutland LE15 8DG
THR No: 28255/0022

If you would like further information about this product or a large print copy of the leaflet:
Contact Brooke Green Ltd, Woodfield House, Moreton Valence, Glos, GL2 7NB.

You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme
at www.mhra.gov.uk/yellowcard. Alternatively you can get a paper Yellow Card form from your
GP's surgery or pharmacy, or call freephone 0808 100 3352 (available 10.00am – 2.00 pm
Monday – Friday).
Leaflet prepared: September 2011
Napiers Cough Soother Herbal Syrup:
This product is available in packs of 100 ml and 200 ml. Not all pack sizes may be marketed.

Traditional Herbal Registration holder and Manufacturer:
Rutland Biodynamics Ltd., Town Park Farm, Brooke, Rutland LE15 8DG

Traditional herbal registration number:
THR 28255/0022

This leaflet was revised 29/09/2011
NL0422 and NL0423

Making medicines safer
You can help to make medicines safer by reporting any side-effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard
Alternatively you can get a paper Yellow Card form from your doctor's surgery or a pharmacy, or call freephone 0808 100 3352 (available 10am-2pm Monday to Friday).

Further Enquiries
A copy of this leaflet in large format print is available.
If you would like more information about this product please contact:
Napier Wholesale
24 Tennant Street, Edinburgh EH6 5ND
Telephone: 0845 002 1860

PATIENT INFORMATION LEAFLET
NAPIERS COUGH SOOTHER HERBAL SYRUP

Please read this leaflet carefully before you start taking this product.
It contains important information for you about this product that may affect you.
Keep this leaflet. You may wish to read it again.
You must contact a doctor, pharmacist or qualified healthcare professional if your symptoms do not improve after 7 days.
If any side effects become serious, or if you notice side effects not listed in here, please tell your doctor, pharmacist or qualified healthcare professional.

What is in this leaflet?
1. What this product is and what it is used for.
2. Before you take this product
3. How to take this product
4. Possible side effects
5. How to store this product
6. Further information
1. WHAT THIS PRODUCT IS AND WHAT IT IS USED FOR

Napier's Cough Soother Herbal Syrup is a traditional herbal medicinal product used for the symptomatic relief of coughs, based on traditional use only.

2. BEFORE YOU TAKE THIS PRODUCT

Do not take this product if you:

- are under 12 years old
- are pregnant or breastfeeding
- are allergic to any of the ingredients
- or to plants of the Asteraceae (Compositae) family such as daisies, marigolds or artichokes (see Section 6)

Important information about some of the ingredients in this medicine

This product contains approx. 4% (v/v) ethanol (alcohol) approximately 316 mg ethanol (alcohol) per dose equivalent to 8 ml of beer or 3.5 ml of wine. Harmful for people suffering from alcoholism or liver-disease.

This product contains sucrose. If you have been told you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.

3. HOW TO TAKE THIS PRODUCT

For oral use only.

Adults and the elderly: Take two 5 ml spoonfuls three times a day.
Children over 12: Take one 5 ml spoonful three times a day.
Do not exceed the stated dose.
This formulation is not suitable for children under 12.
If your symptoms persist after 7 days or worsen, or you have shortness of breath, fever, or green mucus (phlegm), or side effects not mentioned in the leaflet occur, speak to a doctor, pharmacist or healthcare practitioner.

If you take too much (overdose).

If you take more than the recommended dose, speak to a doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you.
Overdose of this product may result in alcohol intoxication and should be treated accordingly.

If you forget to take this product

Continue to take your usual dose at the usual time. It does not matter if you miss a dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this product can have side effects, although not everybody gets them. These include:

Uncommon side effects:
- allergic reactions including contact dermatitis
- digestive upsets (nausea, vomiting or diarrhoea)
- tremors and dizziness
If these persist or become troublesome stop taking the product.
Stop taking this product immediately if you experience any allergic skin reaction.

5. HOW TO STORE THIS PRODUCT

Do not use this product after the expiry date shown on the bottle.
Return any out of date medicine to your pharmacist who will dispose of it for you.
This product does not require any special storage conditions. Keep the bottle tightly closed.
Keep this product out of the reach and sight of children.

6. FURTHER INFORMATION

Each 5 ml of oral liquid contains:

75 microlitres of liquid extract from dried
Pleurisy root* (Asclepias tuberosa L.)
Extraction solvent: Ethanol 35% v/v.

75 microlitres of liquid extract from dried
Elecampane* root (Inula helenium L.)
Extraction solvent: Ethanol 21% v/v.

75 microlitres of liquid extract from dried
White Horehound* leaves and flowering tops (Marrubium vulgare L.)
Extraction solvent: Ethanol 20% v/v.

75 microlitres of liquid extract from dried
Skunk Cabbage root (Symlocospermum foetidus (L.) Salisb.)
Extraction solvent: Ethanol 21% v/v.

112.5 microlitres of Tincture Lobelia Acid from dried Lobelia* herb (Lobelia inflata L.)
Extraction solvents: ethanol 50% v/v and acetic acid 5.8%.

* Certified organically produced herbal ingredient.

This product also contains:

Wild Cherry liquid extract, alcohol (90%), Star Anise oil, Capsicum tincture, caramel, glycerol, sucrose and water.
LABELLING

English Herbal Medicines Horehound Plus Cough Syrup:

A combined Patient Information Leaflet/label is used for this product, this can be found on page 17 of this report.
Brooke Green Horehound Plus Cough Mixture:

A traditional herbal medicinal product used for the symptomatic relief of coughs, based on traditional use only.

Active ingredients:
- Horehound root (L.11)
- Horehound flower (L.11)
- Horehound leaf (L.11)
- Horehound root liquid extract
- Horehound flower liquid extract
- Horehound leaf liquid extract
- Horehound root powder (L.11)
- Horehound flower powder (L.11)
- Horehound leaf powder (L.11)
- Horehound root extract (L.11)
- Horehound flower extract (L.11)
- Horehound leaf extract (L.11)

Dosage:
- Adults and children over 12 years: 15 ml three times a day.
- Children aged 2-12 years: 5 ml three times a day.
- Children under 2 years: consult a healthcare professional.

Storage:
- Store below 25°C.
- Keep out of the reach of children.

Packaging:
- Glass bottle with tamper-evident cap.

Pack size:
- 100 ml

Producer:
- Brooke Green Limited, Mill Lane, Harestall, Peterborough, PE6 9TL, UK.

Certification Mark:
- THR 28255/0022

Ingredients:
- Horehound extract
- Horehound root extract
- Horehound flower extract
- Horehound leaf extract
- Horehound root powder
- Horehound flower powder
- Horehound leaf powder
- Acetic acid
- Propylene glycol
- Water

Usage:
- For the symptomatic relief of coughs.

Cautions:
- Do not use if pregnant or breastfeeding.
- Do not use if allergic to any of the ingredients or to plants of the Acanthaceae (Acanthus) family such as塞手草 or aconite.
- Keep out of the reach and sight of children.

Manufacturer and Traditional Herbal Registration Holder:
- Oakland Herbaceuticals Ltd.
- Town Park Farm, Brooke, Redland, GL3 6GD
- THR 28255/0022
Napiers Cough Soother Herbal Syrup:

Labels
Cartons

NAPIERS THE HERBALISTS

NAPIERS COUGH SOOTHER HERBAL SYRUP
with pleurisy root, eucalyptus, white horehound, skull cabbage and lobelia

A herbal remedy used for the symptomatic relief of coughs, based on traditional use only.

100 ml

PLEASE READ LEAFLET BEFORE USE

Napiers Cough Soother Herbal Syrup is a traditional herbal medicinal product used for the symptomatic relief of coughs, based on traditional use only.

Active ingredients: Each 5 ml of oral liquid contains:

- 25 mg of each of the following:
  - Pleurisy Root
  - Eucalyptus
  - White Horehound
  - Skull Cabbage
  - Lobelia

*Certified organically produced herbal ingredient.
*Contains alcohol (15%)

Shake well before use

Do not take this product:
- If you are under 12 years old
- If you are pregnant or breastfeeding
- Unless prescribed by a doctor
- If you are allergic to any of the ingredients or plants of the Asteraceae (Compositae) family such as daisies, margaritas or asters

How to take:
- For adults and the elderly:
  - Take 5 ml syrup three times a day
  - For children over 12:
  - Take 3 ml syrup three times a day

Your symptoms have not improved after 7 days or are accompanied by fever, or you have difficulty swallowing, sore throat, or unusual bleeding or bruising:
- See healthcare professional
- Do not take on the tongue

Keep out of reach of children

NAPIERS THE HERBALISTS

NAPIERS EDINBURGH 1860 HERB & PLANT REMEDIES

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MHRA PAR; ENGLISH HERBAL MEDICINES HOREHOUND PLUS COUGH SYRUP, BROOKE GREEN HOREHOUND PLUS COUGH MIXTURE, NAPIERS COUGH SOOTHER HERBAL SYRUP, THR 28255/0022