

Allens Pine and Honey Syrup
Covonia Herbal Mucus Cough Syrup

THR 00240/0371

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ALLENS PINE AND HONEY SYRUP
COVONIA HERBAL MUCUS COUGH SYRUP

THR 00240/0371

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Thornton & Ross Ltd a Traditional Herbal Registration Certificate for the traditional herbal medicinal products Allens Pine and Honey Syrup and Covonia Herbal Mucus Cough Syrup (Traditional Herbal Registration number: THR 00240/0371) on 23 April 2013. These products are identical to each other apart from the difference in product name. They are available without prescription and can be bought from pharmacies and other outlets.

Allens Pine and Honey Syrup and Covonia Herbal Mucus Cough Syrup are traditional herbal medicinal products used for relief of the symptoms of mucus coughs and colds, based on traditional use only.

The active ingredients in Allens Pine and Honey Syrup and Covonia Herbal Mucus Cough Syrup come from the root of the Ipecacuanha plant (*Cephaelis ipecacuanha* (Brot.) A. Rich.), the root of the Liquorice plant (*Glycyrrhiza glabra* L.) and the bulb of the Indian Squill plant.

This registration is based exclusively upon evidence of the use of Ipecacuanha root, Liquorice root and Indian Squill bulb 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.

**ALLENS PINE AND HONEY SYRUP
COVONIA HERBAL MUCUS COUGH SYRUP**

THR 00240/0371

SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicinal products Allens Pine and Honey Syrup and Covonia Herbal Mucus Cough Syrup (THR 00240/0371) to Thornton & Ross Ltd on 23 April 2013. These products are on the general sales list (GSL).

A product licence of right (PLR) was originally granted to Thornton & Ross Ltd for this product. The PLR was reviewed and a product licence (PL 00240/5209R) was granted to Thornton & Ross Ltd on 19 April 1989. Following the grant of the Traditional Herbal Registration Certificate, Thornton & Ross Ltd cancelled PL 00240/5209R, with effect from 22 October 2013.

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 to a THR (according to MHRA Guidance dated January 2009). The application falls within the simplified THR application Category B as some modifications were made to the formulation.

PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE: IPECACUANHA ROOT

Scientific name of the plant: *Cephaelis ipecacuanha* (Brot.) A. Rich.

Plant family: Rubiaceae

The herbal substance is controlled by a suitable specification.

HERBAL PREPARATION: IPECACUANHA ROOT LIQUID EXTRACT

Extraction solvent: Ethanol 80% 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: LIQUORICE ROOT

Scientific name of the plant: *Glycyrrhiza glabra* L.

Plant family: Fabaceae

The herbal substance is controlled by a suitable specification.

HERBAL PREPARATION: LIQUORICE ROOT LIQUID EXTRACT

Extraction solvent: Water

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: INDIAN SQUILL BULB

Scientific name of the plant: *Drimia indica* (Roxb.) J P Jessop.

Plant family: Liliaceae

The herbal substance is controlled by a suitable specification.

HERBAL PREPARATION: INDIAN SQUILL BULB LIQUID EXTRACT

Drug extract ratio (DER): 1:5

Extraction solvent: Ethanol 55% 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:**ALLENS PINE AND HONEY SYRUP
COVONIA HERBAL MUCUS COUGH
SYRUP****Description and Composition of the Herbal Product**

The herbal product is a dark brown coloured syrup. 5ml contains 0.007ml of liquid extract from Ipecacuanha root, 0.125ml of liquid extract from Liquorice root and 0.26ml of liquid extract from Indian Squill bulb. The formula also contains the pharmaceutical excipients pumilio pine oil, anise oil, capsicum tincture, arrowroot, menthol, peppermint oil, sucrose, treacle black, honey, acetic acid glacial, sodium benzoate (E211), ethanol and purified water. The formulation is in line with 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

Allens Pine and Honey Syrup is stored in a 150ml amber glass bottle with a child resistant, tamper evident, 28mm cap with a Melinex/aluminium/EPE liner. Covonia Herbal Mucus Cough Syrup is stored in a 150ml or 300ml amber glass bottle embossed with "Covonia" with a child resistant, tamper evident, 28mm cap with a Melinex/aluminium/EPE liner. These types of packaging have been used to store the already licensed products and are satisfactory.

Stability

The product shelf-lives of 36 months when the bottle is unopened and 28 days once the bottle is first opened are acceptable when the storage precautions 'Do not store above 25°C' and 'Store in original container' are applied. This is in line with the already licensed products and is appropriate.

Summary of Product Characteristics, product labels and Patient Information Leaflet

All product literature is in line with that of the already licensed product, with some details amended in line with other products registered under the THR scheme.

ASSESSOR'S OVERALL CONCLUSION

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 are 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 Traditional Herbal Registration.

PRODUCT LITERATURE

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

ASSESSOR'S OVERALL CONCLUSION

It is recommended that a Traditional Herbal Registration can be granted.

CLINICAL ASSESSMENT

INTRODUCTION

The clinical particulars for Allens Pine and Honey Syrup and Covonia Herbal Mucus Cough Syrup are identical to those for the already licensed products. This is satisfactory.

PRODUCT LITERATURE

All product literature is medically satisfactory.

ASSESSOR'S OVERALL CONCLUSION

It is recommended that a Traditional Herbal Registration can be granted.

OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

QUALITY

Allens Pine and Honey Syrup and Covonia Herbal Mucus Cough Syrup are identical to already licensed products. They are, 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.

SAFETY

No new or unexpected safety concerns arose from this application.

BENEFIT-RISK ASSESSMENT

The quality of the products is acceptable and no new preclinical or clinical safety concerns have been identified. The benefit: risk balance is acceptable and a THR should be granted.

**ALLENS PINE AND HONEY SYRUP
COVONIA HERBAL MUCUS COUGH SYRUP**

THR 00240/0371

STEPS TAKEN FOR ASSESSMENT

- 1 The MHRA received the Traditional Herbal Registration application on 20 December 2012
- 2 Following standard checks and communication with the applicant the MHRA considered the application valid on 11 January 2013
- 3 Following assessment of the application the MHRA requested further information relating to the dossier on 25 January 2013
- 4 The applicant responded to the MHRA's request, providing further information on the dossier on 23 April 2013
- 5 A THR was granted on 23 April 2013

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Allens Pine and Honey Syrup
Covonia Herbal Mucus Cough Syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of syrup contains:

0.007ml of extract (as liquid extract) from Ipecacuanha root (*Cephaelis
ipecacuanha* (Brot.) A. Rich.)

Extraction solvent: Ethanol 80% v/v

0.125ml of extract (as liquid extract) from Liquorice root (*Glycyrrhiza glabra*
L.)

Extraction solvent: Water

0.26ml of extract (as liquid extract) from Indian Squill bulb (*Drimia indica*
(Roxb.) J P Jessop (1:5)

Extraction solvent: Ethanol 55% v/v

Each 5ml of oral liquid contains 2.3g of sucrose and 147.6mg of ethanol
(alcohol) (See section 4.4 Special warnings and precautions for use)

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Syrup
A dark brown coloured syrup.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A traditional herbal medicinal product used for relief of the symptoms of
mucus coughs and colds, based on traditional use only.

4.2 Posology and method of administration

For oral use only

Adults, elderly and children over 12 years:-two 5ml spoonfuls every 4 hours as
required, up to a maximum of 4 times per day (40ml).

Duration of use:

Do not use for more than 7 days

If symptoms worsen or persist for more than one week, a doctor or a qualified
healthcare practitioner should be consulted.

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

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients.
Patients with impaired renal function or cardiovascular disorders.
Sensitivity to colophony containing products e.g. some lipsticks and eyeshadows etc.
(possibly due to excipient Pumilio Pine Oil)

4.4 Special warnings and precautions for use

Do not exceed the stated dose.

Contains Sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

It also contains 3.7% vol ethanol (alcohol), i.e. up to 295mg per 10 ml dose, equivalent to 7.5ml beer, or 3.1 ml wine per dose. Harmful for those suffering from alcoholism. To be taken into account in children, pregnant women and high-risk groups such as patients with liver disease or epilepsy’.

The use in children and adolescents under 12 years of age has not been established due to lack of adequate data.

Patients taking liquorice medication should not take other liquorice containing products as serious adverse events may occur such as water retention, hypokalemia, hypertension, cardiac rhythm disorders.

Liquorice medication should be used with caution in patients affected by hypertension, kidney diseases, liver or cardiovascular disorders or hypokalemia as they are more sensitive to the adverse effects of liquorice.

If symptoms worsen or persist for more than one week, a doctor or a qualified healthcare practitioner should be consulted.

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

4.5 Interaction with other medicinal products and other forms of interaction

Liquorice root may counteract antihypertensive action of prescribed medications.

Not to be used concomitantly with thiazide diuretics, cardiac glycosides, corticosteroids, stimulant laxatives or other medications which may aggravate electrolyte imbalance.

In view of the potential for Squill to interact with other medicines administered concurrently, the product should not be taken with digoxin or any medicines for a heart condition.

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 Allens Pine & Honey Balsam/Covonia Herbal Mucus Cough Syrup during pregnancy and lactation has not been established. The use during pregnancy and lactation is not recommended.

Studies on fertility have not been performed.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive or operate machines have been performed.

This product contains alcohol (see section 2)

4.8 Undesirable effects

Adverse effects of both squill and ipecacuanha include nausea and vomiting caused by their irritant effect on the gastrointestinal tract; squill can also cause diarrhoea. Absorption of emetine known to accumulate in muscle after ingestion of larger doses of ipecacuanha, may interfere with muscle fibre contractility of heart muscle.

The frequency is not known.

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

4.9 Overdose

The symptoms of overdose of squill and ipecacuanha include nausea and vomiting. Treatment of overdose would depend upon the symptoms, cardiac irregularities, which may be caused by squill, may be treated by emesis or aspiration and lavage. In cases of severe cardiac arrhythmias, potassium and/or anti-arrhythmic agents may be given. Prolonged vomiting may be a symptom of overdose of ipecacuanha alkaloids, which may be controlled by intramuscular injection of 25 -50mg of chlorpromazine or of a comparable dose of a related phenothiazine; fluid and electrolyte imbalance should also be corrected.

Cases of overdose with liquorice root have been reported with prolonged use (more than 4 weeks) and/or intake of high amount of liquorice, with symptoms such as water retention, hypokalaemia, hypertension, cardiac rhythm disorders, hypertensive encephalopathy.

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.

A study has shown that 18 β -glycyrrhetic acid crosses through the placental barrier and can be detected in the rat foetuses. Following feeding of dams with 100 mg 18 β -glycyrrhetic acid/kg/day commencing on the 13th day of gestation, on the 17th, 19th and 21st days of gestation the maternal plasma 18 β -glycyrrhetic acid concentrations were approximately 100 μ g/ml, whereas the foetal concentrations were 5, 18 and 32 μ /ml, respectively. In developmental toxicity studies, glycyrrhizin (ammonium salt) exhibited some embryotoxicity to the developing rat foetus, but the foetal effects were considered as minor. These effects were shown at the dose of 100 and 250 mg/kg of ammonium glycyrrhizin from 7th to 20th day of pregnancy (soft-tissue abnormalities, mostly renal, and external haemorrhages) and at the dose of 1000 mg/kg of 18 β -glycyrrhetic acid from the 13th day of gestation (significant reduction in lamellar body content of lungs and reduced number alveolar lamellar body and surfactant clusters, but no apparent increase in malformation or foetal death rate).

Another study suggested that 100 mg/kg of liquorice extract repeated for 7 days may also aggravate body weight loss and malformations of foetuses, induced by intrauterine exposure to cyclophosphamide.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pumilio Pine Oil
Anise oil
Capsicum tincture
Arrowroot
Menthol
Peppermint oil
Sucrose
Treacle black
Honey
Acetic Acid Glacial
Sodium Benzoate (E211)
Ethanol
Purified water

6.2 Incompatibilities

None known

- 6.3 Shelf life**
36 months unopened.
Once opened use within 28 days
- 6.4 Special precautions for storage**
Store below 25°C. Store in original container.
- 6.5 Nature and contents of container**
150ml bottle-amber glass with a child resistant tamper evident 28mm cap with a Melinex/Aluminium/EPE liner.
- 150ml, 300ml Amber glass bottle embossed “Covonia” with a child resistant tamper evident 28mm cap with Melinex/Aluminium/EPE liner.
- 6.6 Special precautions for disposal**
No special requirements
- 7 MARKETING AUTHORISATION HOLDER**
Thornton & Ross Ltd.,
Linthwaite Laboratories,
Huddersfield,
HD7 5QH
- 8 MARKETING AUTHORISATION NUMBER(S)**
THR 00240/0371
- 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**
23/04/2013
- 10 DATE OF REVISION OF THE TEXT**
23/04/2013

PRODUCT INFORMATION LEAFLET

All necessary patient information is included on the following product labelling.

LABELLING

Allens Pine and Honey Syrup

Label:



Carton:

	163741	<p>Do not store above 25°C. Store in original container. Use within 28 days of first opening. Some deposits may form on storage. This is normal and can be mixed by shaking. Traditional Herbal Registration Holder and Manufacturer: Thornton and Ross Ltd., Huddersfield, HD7 5QH, UK. THR 00240/0371 22460811</p> <p>150ml </p>  <p>5 011309 605518 ></p>
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<p style="writing-mode: vertical-rl; transform: rotate(180deg);">▶ IMPORTANT: Peel here & read all text inside BEFORE use ▶</p>	<p>Allens Pine & Honey Syrup is a traditional herbal medicinal product used for relief of the symptoms of mucus coughs and colds based on traditional use only.</p> <p>SHAKE THE BOTTLE. Take the syrup by mouth.</p> <p>Adults, the elderly and children over 12 years: Take 2 x 5ml spoonfuls every 4 hours if required but not more than 4 doses (40ml) in any 24 hours.</p> <p>Not recommended for children under 12 years.</p> <p>Do not use for more than 7 days.</p> <p>DO NOT EXCEED THE STATED DOSE. Peel where shown for further precautions.</p> <p>Keep out of the sight and reach of children.</p> <p>Active ingredients per 5ml of syrup: 0.007ml liquid extract Ipecacuanha root, 0.125ml liquid extract Liquorice root, 0.26ml liquid extract Indian Squill bulb.</p> <p>Also contains: Each 5ml of syrup contains 2.3g of sucrose and 0.19ml of ethanol (alcohol).</p> <p>See reverse for full list.</p>	163741	<p>Allens Pine & Honey Syrup contains extracts of liquorice, ipecacuanha and squill which belong to a group of medicines known as expectorants. They help remove phlegm in people with chesty coughs and colds. P1</p> <p>1. Before you use this medicine</p> <p>■ Do not use the medicine if you have...</p> <ul style="list-style-type: none"> • An allergy to any of the ingredients listed in section 3. • An allergy to colophony (pine resin) which is contained in some cosmetic products e.g. lipsticks and eyeshadow. • Any type of heart or circulation complaint. • Kidney problems. <p>Do not take with other liquorice containing medicines as serious side effects may occur eg. water retention, high blood pressure, irregular heartbeat.</p> <p>If symptoms worsen or persist for more than 1 week consult your doctor or qualified healthcare practitioner.</p> <p>■ If you are taking any of the following medicines, do not take this medicine and consult your doctor:</p> <ul style="list-style-type: none"> • For any heart problems or high blood pressure. • Corticosteroids. • Digoxin or any medicines for a heart condition. • Stimulant laxatives e.g. senna. • Medicines that may affect potassium or sodium levels in the body. • Medicines which may interact with alcohol e.g. metronidazole. <p>■ Consult your doctor before taking this medicine if you have high blood pressure, a liver disorder or low potassium levels (hypokalemia).</p>
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<p>■ If you have difficulty breathing, fever or discoloured green phlegm talk to your doctor.</p> <p>■ Pregnant or breastfeeding... Do not use if you are pregnant or are breastfeeding.</p> <p>■ Important ingredient information</p> <ul style="list-style-type: none"> • Contains 2.3g of sucrose per 5ml dose. If you have an intolerance to some sugars, contact your doctor before taking this medicine. • It also contains 3.7% vol ethanol (alcohol), i.e. up to 295mg per 10ml dose, equivalent to 7.5ml beer, or 3.1ml wine per dose. Harmful for those suffering from alcoholism. To be taken into account in children, pregnant women and high risk groups such as patients with liver disease or epilepsy. • If affected by alcohol, do not drive or use machines. <p>2. Possible side effects: Like all medicines, Allens Pine & Honey Syrup can have side effects, although these don't affect everyone.</p> <p>Possible side effects are:</p> <ul style="list-style-type: none"> • Feeling sick or being sick. • Diarrhoea. • Heart problems. • Low blood potassium levels which can cause muscle weakness or twitching. <p>If you notice these or any other side effect not included above, stop use and tell your doctor or pharmacist. They will tell you what to do.</p> <p>3. Further information</p> <p>■ If you accidentally take too much see a doctor straight away. Take the pack with you to show which medicine you have swallowed.</p> <ul style="list-style-type: none"> • Do not use after the expiry date. The expiry date refers to the last day of that month. • Return any unused medicine to the pharmacy for disposal. 	P2	<p>The active ingredients per 5ml of syrup are: 0.007ml liquid extract from Ipecacuanha root (<i>Cephaelis ipecacuanha</i> (Brot.) A. Rich.) Extract solvent: Ethanol 80% v/v, 0.125ml liquid extract from Liquorice root (<i>Glycyrrhiza glabra</i> L.) Extract solvent: water, 0.26ml liquid extract from Indian Squill bulb (<i>Drimia indica</i> (Roxb.) JP Jessop (1.5) Extract solvent: Ethanol 55% v/v. P3</p> <p>The other ingredients are: pumilio pine oil, capsicum tincture (capsicum oleoresin), arrowroot, menthol, peppermint oil, anise oil, sucrose, black treacle, honey, acetic acid glacial, sodium benzoate (E211), ethanol and purified water.</p> <p>What the medicine looks like Allens Pine & Honey Syrup is a dark brown syrupy liquid. It is supplied in 150ml bottles.</p> <p>This label was revised in April 2013</p> <div style="text-align: center; margin-top: 10px;">  <p>THR Certification Mark</p> </div>	22460811
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Covonia Herbal Mucus Cough Syrup

150 ml pack label:



300 ml pack label:



Carton:



<p>▶ IMPORTANT: Peel here & read all text inside BEFORE use. ◀</p>	<p>Covonia Herbal Mucus Cough Syrup is a traditional herbal medicinal product used for relief of the symptoms of mucus coughs and colds based on traditional use only.</p> <p>SHAKE THE BOTTLE. Take the syrup by mouth.</p> <p>Adults, the elderly and children over 12 years: Take 2 x 5ml spoonfuls every 4 hours if required but not more than 4 doses (40ml) in any 24 hours.</p> <p>Not recommended for children under 12 years.</p> <p>Do not use for more than 7 days.</p> <p>DO NOT EXCEED THE STATED DOSE.</p> <p>Peel where shown for further precautions.</p> <p>Keep out of the sight and reach of children.</p> <p>Active ingredients per 5ml of syrup: 0.007ml liquid extract Ipecacuanha root, 0.125ml liquid extract Licorice root, 0.26ml liquid extract Indian Squill bulb.</p> <p>Also contains: Each 5ml of syrup contains 2.3g of sucrose and 0.19ml of ethanol (alcohol).</p> <p>See reverse for full list.</p>	<p>163739</p>	<p>Covonia Herbal Mucus Cough Syrup contains extracts of liquorice, ipecacuanha and squill which belong to a group of medicines known as expectorants. They help remove phlegm in people with chesty coughs and colds.</p> <p>1. Before you use this medicine</p> <p>■ Do not use the medicine if you have...</p> <ul style="list-style-type: none"> • An allergy to any of the ingredients listed in section 3. • An allergy to colophony (pine resin) which is contained in some cosmetic products e.g. lipsticks and eyeshadow. • Any type of heart or circulation complaint. • Kidney problems. <p>Do not take with other liquorice containing medicines as serious side effects may occur eg. water retention, high blood pressure, irregular heartbeat.</p> <p>If symptoms worsen or persist for more than 1 week consult your doctor or qualified healthcare practitioner.</p> <p>■ If you are taking any of the following medicines, do not take this medicine and consult your doctor:</p> <ul style="list-style-type: none"> • For any heart problems or high blood pressure. • Corticosteroids. • Digoxin or any medicines for a heart condition. • Stimulant laxatives e.g. senna. • Medicines that may affect potassium or sodium levels in the body. • Medicines which may interact with alcohol e.g. metronidazole. <p>■ Consult your doctor before taking this medicine if you have high blood pressure, a liver disorder or low potassium levels (hypokalaemia).</p>
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<p>■ If you have difficulty breathing, fever or discoloured green phlegm talk to your doctor.</p> <p>■ Pregnant or breastfeeding... Do not use if you are pregnant or are breastfeeding.</p> <p>■ Important ingredient information</p> <ul style="list-style-type: none"> • Contains 2.3g of sucrose per 5ml dose. If you have an intolerance to some sugars, contact your doctor before taking this medicine. • It also contains 3.7% vol ethanol (alcohol), i.e. up to 295mg per 10ml dose, equivalent to 7.5ml beer, or 3.1ml wine per dose. Harmful for those suffering from alcoholism. To be taken into account in children, pregnant women and high risk groups such as patients with liver disease or epilepsy. • If affected by alcohol, do not drive or use machines. <p>2. Possible side effects: Like all medicines Covonia Herbal Mucus Cough Syrup can have side effects, although these don't affect everyone.</p> <p>Possible side effects are:</p> <ul style="list-style-type: none"> • Feeling sick or being sick. • Diarrhoea. • Heart problems. • Low blood potassium levels which can cause muscle weakness or twitching. <p>If you notice these or any other side effect not included above, stop use and tell your doctor or pharmacist. They will tell you what to do.</p> <p>3. Further information</p> <p>■ If you accidentally take too much see a doctor straight away. Take the pack with you to show which medicine you have swallowed.</p> <ul style="list-style-type: none"> • Do not use after the expiry date. The expiry date refers to the last day of that month. • Return any unused medicine to the pharmacy for disposal. 	<p>P2</p>	<p>The active ingredients per 5ml of syrup are: 0.007ml liquid extract from Ipecacuanha root (<i>Cephaelis ipecacuanha</i> (Brot.) A. Rich.) Extract solvent: Ethanol 80% v/v, 0.125ml liquid extract from Licorice root (<i>Glycyrrhiza glabra</i> L.) Extract solvent: water, 0.26ml liquid extract from Indian Squill bulb (<i>Drimys indica</i> (Roxb.) JP Jessop (1:5) Extract solvent: Ethanol 55% v/v.</p> <p>The other ingredients are: pumilio pine oil, capsicum tincture (capsicum oleoresin), arrowroot, menthol, peppermint oil, anise oil, sucrose, black treacle, honey, acetic acid glacial, sodium benzoate (E211), ethanol and purified water.</p> <p>What the medicine looks like Covonia Herbal Mucus Cough Syrup is a dark brown syrupy liquid. It is supplied in 150ml and 300ml bottles.</p> <p>This label was revised in April 2013</p> <div style="text-align: center;">  <p>THR Certification Mark</p> </div>	<p>24315703</p>
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