Covonia Catarrh Relief Formula

(Each 5ml contains:-
Liquid Extract Boneset (1:1 21% alcohol) 0.6ml
Liquid Extract Blue Flag (1:1 37% alcohol) 0.05ml
Liquid Extract Burdock Root (1:1 21% alcohol) 0.25ml
Liquid Extract Hyssop (1:1 21% alcohol) 0.35ml)

PL 00240/0142

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PL 00240/0142

LAY SUMMARY

The MHRA granted Thornton & Ross Ltd, a Marketing Authorisation (licence) for the medicinal product Covonia Catarrh Relief Formula PL 00240/0142. This product is a General Sales List (GSL) herbal remedy traditionally used for the symptomatic relief of nasal catarrh and catarrh of the throat.

Each 5 ml of Covonia Catarrh Relief Formula contains the active ingredients: Liquid Extract Boneset (1:1 21% alcohol) 0.6ml; Liquid Extract Blue Flag (1:1 37% alcohol) 0.05ml; Liquid Extract Burdock Root (1:1 21% alcohol) 0.25ml; and Liquid Extract Hyssop (1:1 21% alcohol) 0.35ml.

This is a simple abridged application that cross refers to Potters Catarrh mixture (PL 00250/5051R) which was granted on the 5th June 1989 and, as such, these products can be used interchangeably.

No new or unexpected safety concerns arose from this simple application and it is, therefore, judged that the benefits of taking Covonia Catarrh Relief Formula outweigh the risks, therefore a Marketing Authorisation has been granted.

Covonia Catarrh Relief Formula

(Each 5ml contains:-
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PL 00240/0142

SCIENTIFIC DISCUSSION

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INTRODUCTION

The UK granted a marketing authorisation for the medicinal product Covonia Catarrh Relief Formula PL 00240/0142 to Thornton & Ross Ltd on the 22nd February 2006. This product is a General Sales List medicine.

This marketing authorisation is an informed consent abridged application according to article 10.1(a) (i) of Directive 2001/83/EC. It has demonstrated essential similarity to the cross-reference product, Potters Catarrh mixture (PL 00250/5051R) which was granted on the 5th June 1989.

No new data was submitted nor was it necessary for this simple application, as the data is identical to that of the previously approved cross-reference product. As the cross-reference product was granted prior to the introduction of current legislation, no Public Assessment Report has been generated for it.

Every 5ml of this product contains the active ingredients: Liquid Extract Boneset (1:1 21% alcohol) 0.6ml; Liquid Extract Blue Flag (1:1 37% alcohol) 0.05ml; Liquid Extract Burdock Root (1:1 21% alcohol) 0.25ml; and Liquid Extract Hyssop (1:1 21% alcohol) 0.35ml. These ingredients are indicated for the symptomatic relief of nasal catarrh and catarrh of the throat.

PHARMACEUTICAL ASSESSMENT

LICENCE NO:	PL 00240/0142
PROPRIETARY NAME:	Covonia Catarrh Relief Formula
ACTIVES (per 5ml):	Liquid Extract Boneset (1:1 21% alcohol) 0.6ml; Liquid Extract Blue Flag (1:1 37% alcohol) 0.05ml; Liquid Extract Burdock Root (1:1 21% alcohol) 0.25ml; Liquid Extract Hyssop (1:1 21% alcohol) 0.35ml.
COMPANY NAME:	Thornton & Ross Ltd
E.C. ARTICLE:	Article 10.1(a)(i) of Directive 2001/83/EC
LEGAL STATUS:	GSL

1. INTRODUCTION

This is an informed consent application for Covonia Catarrh Relief Formula submitted under Article 10.1(a)(i) of Directive 2001/83/EC. The proposed MA holder is Thornton & Ross Ltd, Linthwaite, Huddersfield, HD7 5QH.

This application cross refers to the marketing authorisation for Potters Catarrh mixture (PL 00250/5051R) which is approved in the UK. This application is considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name for this product is Covonia Catarrh Relief Formula. The product has been named in line with the current requirements.

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

Every 5 ml of this product contains Liquid Extract Boneset (1:1 21% alcohol) 0.6ml; Liquid Extract Blue Flag (1:1 37% alcohol) 0.05ml; Liquid Extract Burdock Root (1:1 21% alcohol) 0.25ml; Liquid Extract Hyssop (1:1 21% alcohol) 0.35ml.

The immediate container for Covonia Catarrh Relief Formula is a Glass bottle with polypropylene screwcap and the sizes are 150ml and 200ml.

The proposed shelf-life (3 years) and storage conditions (None) are consistent with the details registered for the cross-reference product.

2.3 Legal status

On approval, the product will be a General Sales List medicine.

2.4 Marketing authorisation holder/Contact Persons/Company

The proposed Marketing Authorisation holder is Thornton & Ross Ltd, Linthwaite, Huddersfield, HD7 5QH.

The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers

Evidence of GMP compliance has been provided for the proposed manufacturing sites.

2.6 Qualitative and quantitative composition

The proposed compositions are consistent with the details registered for the cross-reference product.

2.7 Manufacturing process

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

2.8 Finished product/shelf-life specification

The proposed finished product specification is in line with the details registered for the cross-reference product.

2.9 Drug substance specification

The proposed drug substance specification for this product is consistent with the details registered for the cross-reference product.

2.10 TSE Compliance

No materials of animal or human origin are included in the product. This is consistent with the cross reference product.

3. EXPERT REPORTS

Satisfactory statements have been provided.

4. PRODUCT NAME & APPEARANCE

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

5. SUMMARY OF PRODUCT CHARACTERISTICS

The proposed SPC is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET/CARTON

PIL

The patient information leaflet has been prepared in-line with the details registered for the cross-reference product.

Labelling

The proposed artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements.

7. CONCLUSIONS

The data submitted with the application is acceptable. A Marketing Authorisation should be granted.

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 an informed consent abridged application for PL 00240/0142, 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

Liquid Extract Boneset (1:1 21% alcohol) l; Liquid Extract Blue Flag (1:1 37% alcohol); Liquid Extract Burdock Root (1:1 21% alcohol); and Liquid Extract Hyssop (1:1 21% alcohol) are all well known herbal extracts and have been used for the symptomatic relief of nasal catarrh and catarrh of the throat for many years.

This application is identical to a previously granted application Potters Catarrh mixture (PL 00250/5051R).

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 and so interchangeable. Extensive clinical experience with Liquid Extract Boneset, Liquid Extract Blue Flag, Liquid Extract Burdock Root and with Liquid Extract Hyssop is considered to have demonstrated the therapeutic value of this compound. The risk benefit is therefore considered to be positive.

Covonia Catarrh Relief Formula

(Each 5ml contains:-
Liquid Extract Boneset (1:1 21% alcohol) 0.6ml
Liquid Extract Blue Flag (1:1 37% alcohol) 0.05ml
Liquid Extract Burdock Root (1:1 21% alcohol) 0.25ml
Liquid Extract Hyssop (1:1 21% alcohol) 0.35ml)

PL 00240/0142

STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation application on the 01/02/2005.
2	Following standard checks and communication with the applicant the MHRA considered the application valid on 16/09/2005.
3	Following assessment of the application the MHRA requested further information on the 30/09/2005.
4	The applicant responded to the MHRA's requests, providing further information on 29/11/2005.
7	The application was determined on 22/02/2006.

Covonia Catarrh Relief Formula

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PL 00240/0142

STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

Covonia Catarrh Relief Formula

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PL 00240/0142

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Covonia Catarrh Relief Formula

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains:-
Liquid Extract Boneset (1:1 21% alcohol) 0.6ml
Liquid Extract Blue Flag (1:1 37% alcohol) 0.05ml
Liquid Extract Burdock Root (1:1 21% alcohol) 0.25ml
Liquid Extract Hyssop (1:1 21% alcohol) 0.35ml

3 PHARMACEUTICAL FORM

Oral Liquid

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A herbal remedy traditionally used for the symptomatic relief of nasal catarrh and catarrh of the throat.

4.2 Posology and method of administration

Adults and the Elderly (only): One 5ml spoonful three times a day.
Children over 12: One 5ml spoonful morning and evening
Children under 12: Not recommended

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

This medicinal product contains 11.5 vol% ethanol (alcohol), i.e. up to 453mg per dose, equivalent to 12 ml beer, 5 ml wine per dose
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.

4.5 Interaction with other medicinal products and other forms of interaction

Refer to 4.4

4.6 Pregnancy and lactation

There are no adequate date from the use of Covonia Catarrh Relief Formula in pregnant women. Covonia Catarrh Relief Formula should not be used in pregnancy.

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

None

4.9 Overdose

No cases known.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Boneset and Hyssop are specific herbal anticatarrhals. Boneset is also immune-stimulant.

5.2 Pharmacokinetic properties

No information available.

5.3 Preclinical safety data

No information available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chloroform spirit (containing chloroform, ethanol and purified water), Methyl Parahydroxybenzoate (E218), Tincture Capsicum (containing capsicum oleoresin, ethanol and water), Caramel (E150), Glycerol (E422) and Purified Water

6.2 Incompatibilities

None

6.3 Shelf life

Three years.

6.4 Special precautions for storage

None

6.5 Nature and contents of container

Glass bottle with polypropylene screwcap: 150ml and 200ml.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd, Linthwaite, Huddersfield, West Yorkshire, HD7 5QH, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/0142

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22/02/2006

10 DATE OF REVISION OF THE TEXT

22/02/2006

11 DOSIMETRY (IF APPLICABLE)

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

Covonia Catarrh Relief Formula
PL 00240/0142
Patient Information Leaflet

PATIENT INFORMATION LEAFLET

COVONIA

CATARRH RELIEF FORMULA

Read all of this leaflet carefully because it contains important information for you. Keep this leaflet. You may need to refer to it again. Ask your pharmacist or doctor if you need further information or advice.

What is in Your Medicine
Each 5ml dose contains Liquid Extract Boneset 0.6ml, Liquid Extract Blue Flag 0.05ml, Liquid Extract Burdock Root 0.25ml, Liquid Extract Hyssop 0.35ml as the active ingredients.
It also contains Chloroform Spirit (containing chloroform, ethanol and purified water), Methyl Parahydroxybenzoate (E218), Tincture Capsicum (containing capsicum oleoresin, ethanol and purified water), Caramel (E150), Glycerol (E422) and Purified Water.

About Your Medicine
Covonia Catarrh Relief Formula is an oral liquid containing extracts of Boneset, Blue Flag, Burdock Root and Hyssop. Boneset and Hyssop are specific herbal anticatarrhals. Boneset is also an immune-stimulant. This medicine is a herbal remedy traditionally used for relief of the symptoms of nasal catarrh and catarrh of the throat.
This medicine is available in bottles containing 150ml and 200ml of liquid.

Who Makes This Medicine
The Marketing Authorisation Holder is Thornton & Ross Ltd., Huddersfield, HD7 5QH, UK.
The Manufacturer is Potter's (Herbal Supplies) Ltd, Leyland Mill Lane, Wigan, WN1 2SB, UK.

Before You Take this Medicine
Do not take this medicine if:
* You are hypersensitive to any of the ingredients listed.
* You are pregnant or breast feeding.

Further information about some of the ingredients in this medicine.
This medicinal product contains 11.5 vol% ethanol (alcohol), i.e. up to 453mg per dose, equivalent to 12ml beer, or 5ml wine per dose. Harmful for those suffering from alcoholism.

M159

To be taken into account in pregnant or breast feeding women, children and high-risk groups such as patients with liver disease or epilepsy.

This product contains Methyl Parahydroxybenzoate (E218) which may cause allergic reactions, possibly delayed.

How To Take This Medicine
Dosage: For oral use.
Adults and the Elderly: Take one 5ml spoonful three times a day.
Children over 12 years: Take one 5ml spoonful morning and evening.
Children under 12 years: Not recommended.

DO NOT EXCEED THE STATED DOSE.

If symptoms persist or worsen or you are unclear about using this medicine consult your doctor or pharmacist.
If you accidentally take too much see a doctor straight away and take your medicine with you to show which product you have taken.

Possible Side Effects
There are no known side effects associated with the use of this medicine. If you notice any effects stop using this medicine and tell your doctor or pharmacist.

Storing Your Medicine
There are no special storage conditions, but as with all medicines keep it out of the reach and sight of children.

Do not use after the expiry date which is stated on the pack.

Leaflet Prepared: December 2005 M159

Purpose of Artwork / CMJ Generation	Piggyback Licence Application				Pantone Refs:
Product Name:	Covonia Catarrh Relief Formula				Black
Pack size:	150ml	File Ref:	M159 NIC (13721) P5		
Component Dimensions:	210 x 148 flat (26 x 148mm Folded)	Component:	Leaflet		
Approved & Date:					

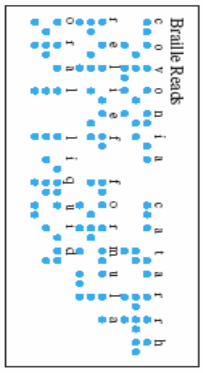
Covonia Catarrh Relief Formula
PL 00240/0142
Container label

Purpose of Artwork/ CMU Generation	Piggy back licence application			Pantone Refs:
Product Name:	Covonia Catarrh Relief Formula			Pantone 372
Pack size:	150ml	File Ref:	M161 (13719)GB P3	Pantone 376
Component Dimensions:	42 x 100 mm	Component:	Label	Pantone 356
Approved & Date:				Pantone 485
				Black

Covonia Catarrh Relief Formula
PL 00240/0142
Outer Carton Label

Purpose of Artwork/ CMU Generation:	Piggy back licence application			Pantone Refs:
Product Name:	Covonia Catarrh Relief Formula			Pantone 372 Pantone 376 Pantone 356 Pantone 485 Black
Pack size:	150ml	File Ref:	M160 (13720)GB P4	
Component Dimensions:	112 x 50 x 50 mm	Component:	Carton	
Approved & Date:				

Covonia Catarrh Relief Formula
PL 00240/0142
Outer Carton Label



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				Pantone Refs:
Purpose of Artwork/ CMU Generation	Piggy back licence application			
Product Name:	Covonia Catarrh Relief Formula			Pantone 372
Pack size:	150ml	File Ref:	M160 (13720)GB P4	Pantone 376
Component Dimensions:	112 x 50 x 50 mm	Component:	Carton	Pantone 356
Approved & Date:				Pantone 485
				Black

MHRA PAR Covonia Catarrh Relief Formula
(Each 5ml contains:- Liquid Extract Boneset (1:1 21% alcohol) 0.6ml Liquid Extract Blue Flag (1:1 37% alcohol) 0.05ml Liquid Extract Burdock Root (1:1 21% alcohol) 0.25ml Liquid Extract Hyssop (1:1 21% alcohol) 0.35ml)
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