THORNTON AND ROSS COLD & FLU FORMULA ORAL SOLUTION

(paracetamol, guafenesin, phenylephrine hydrochloride, cetylpyridinium chloride)

PL 00240/0144

UK Public Assessment Report

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PL 00240/0144

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted Thornton & Ross Limited a Marketing Authorisation (licence) for the medicinal product Thornton & Ross Cold & Flu Formula Oral Solution (PL 00240/0144) on 5th March 2008. This is a P licensed medicine available from pharmacies.

Thornton & Ross Cold & Flu Formula Oral Solution contains four active ingredients - paracetamol, guafenesin, phenylephrine hydrochloride, and cetylpyridinium chloride. Paracetamol is an analgesic (relieves pain) and an antipyretic (lowers your temperature when you have a fever). Guafenesin is an expectorant which loosens phlegm, and so relieves chesty coughs. Phenylephrine hydrochloride is a decongestant, and opens up the airways in the nose and sinuses to help you breathe more easily. Cetylpyridinium chloride is an antiseptic and anti-infective which relieves dry tickly sore throats.

Thornton & Ross Cold & Flu Formula Oral Solution provides short term relief of cold and flu symptoms, including aches and pains, headache, blocked nose and sinuses, dry tickly sore throat, and chesty coughs.

This application is a duplicate of a previously granted application for Covonia Cold & Flu Formula (PL 00240/0134), held by Thornton & Ross Limited. The test and reference products are identical.

No new or unexpected safety concerns arose from this simple application and it was therefore judged that the benefits of taking Thornton & Ross Cold & Flu Formula Oral Solution outweigh the risks; hence a Marketing Authorisation has been granted.

THORNTON AND ROSS COLD & FLU FORMULA ORAL SOLUTION

(paracetamol, guafenesin, phenylephrine hydrochloride, cetylpyridinium chloride)

PL 00240/0144

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the MHRA granted Thornton & Ross Limited a Marketing Authorisation (MA) for the medicinal product Thornton & Ross Cold & Flu Formula Oral Solution (PL 00240/0144) on 5th March 2008. The product is a P licensed medicine available from pharmacies.

The application was submitted as a simple abridged application according to article 10c of Directive 2001/83/EC (as amended), cross-referring to Covonia Cold & Flu Formula (PL 00240/0134, Thornton & Ross Limited), approved on 5th April 2004, and originally authorised as Galpharm Flu Relief Solution (PL 16028/0078, Galpharm Healthcare Limited) on 6th February 2004.

No new data were submitted nor was it necessary for this simple application, as the data are 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 PAR was generated for it.

Thornton & Ross Cold & Flu Formula Oral Solution contains a combination of four active ingredients - paracetamol, guafenesin, phenylephrine hydrochloride, and cetylpyridinium chloride.

Paracetamol has analgesic and antipyretic actions probably due to the inhibition of prostaglandin biosynthesis. It is effective against pain of mild to moderate severity, but is less successful against chronic pain. Guafenesin is an expectorant which reduces the viscosity of tenacious sputum, and so relieves chesty coughs. Phenylephrine hydrochloride is a sympathomimetic agent with mainly direct effect on adrenergic receptors. It has predominantly alpha-adrenergic activity and is without significant stimulating effects on the central nervous system at usual doses. It may be given orally to relieve nasal congestion. Cetylpyridinium Chloride is a cationic disinfectant with bactericidal activity against Gram-positive and, at higher concentration against some Gram-negative organisms. Cetylpyridinium Chloride may be used in a variety of preparations for the local treatment of minor infections.

Thornton & Ross Cold & Flu Formula Oral Solution is indicated for the short term relief of cold and flu symptoms, including aches and pains, headache, blocked nose and sinuses, dry tickly sore throat, and chesty coughs.

PHARMACEUTICAL ASSESSMENT

LICENCE NUMBER:	PL 00240/0144
PROPRIETARY NAME:	Thornton & Ross Cold & Flu Formula Oral Solution
ACTIVE INGREDIENT/S:	paracetamol, guafenesin, phenylephrine hydrochloride, & cetylpyridinium chloride
COMPANY NAME:	Thornton & Ross Limited
E.C. ARTICLE:	Article 10c of Directive 2001/83/EC (as amended)
LEGAL STATUS:	P

1. INTRODUCTION

This is a simple abridged application, submitted under Article 10c of Directive 2001/83/EC (as amended) for Thornton & Ross Cold & Flu Formula Oral Solution. The proposed MA holder is 'Thornton & Ross Limited, Linthwaite Laboratories, Huddersfield, HD7 5QH, United Kingdom'.

The reference product is Covonia Cold & Flu Formula (PL 00240/0134), held by Thornton & Ross Limited. The test and reference products are identical.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 Name(s)

The proposed name of the product is Thornton & Ross Cold & Flu Formula Oral Solution. The product has been named in line with current requirements.

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

The product contains the active ingredients paracetamol, guafenesin, phenylephrine hydrochloride, and cetylpyridinium chloride. Each 20ml dose of solution contains 1000mg of paracetamol, 200mg guafenesin, 12.18mg phenylephrine hydrochloride, and 3mg cetylpyridinium chloride. The container closure system is either clear type III glass bottles, or clear PET bottles, both 160ml in size and having a polypropylene child resistant closure. A graduated polypropylene measuring cup is provided as the administration device with all packs of the product.

The proposed shelf-life (2 years) and storage conditions (Do not store above 25^{o}C; Keep the container in the outer carton; Keep the container tightly closed) are consistent with the details registered for the cross-reference product.

2.3 Legal status

The product is a P licensed medicine available by supply through pharmacies.

2.4 Marketing authorisation holder / Contact Persons / Company

The proposed Marketing Authorisation holder is 'Thornton & Ross Limited, Linthwaite Laboratories, Huddersfield, HD7 5QH, United Kingdom'.

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

2.5 Manufacturers

The proposed manufacturing site is consistent with that registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition

The proposed composition is 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 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.

3. EXPERT REPORTS

Satisfactory expert reports and curriculum vitae of experts are 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 (SmPC)

The approved SmPC is consistent with the details registered for the cross-reference product.

6. PATIENT INFORMATION LEAFLET (PIL) / CARTON

PIL

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

Carton and bottle label

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

7. CONCLUSIONS

The grounds for this application are considered adequate. It is recommended that a Marketing Authorisation is granted for this application.

PRECLINICAL ASSESSMENT

The application was submitted as a simple abridged application according to article 10c of Directive 2001/83/EC (as amended).

No new preclinical data have been supplied with this application and none are required for an application of this type. A preclinical expert report has been written by a suitably qualified person and is satisfactory.

CLINICAL ASSESSMENT

The application was submitted as a simple abridged application according to article 10c of Directive 2001/83/EC (as amended).

As this is a duplicate application for PL 00240/0134, no new clinical data have been supplied with the application 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

This application is identical to the previously granted application for Covonia Cold & Flu Formula (PL 00240/0134).

No new or unexpected safety concerns arise from this application.

PRODUCT LITERATURE

The approved SmPC, PIL and labelling are satisfactory and consistent with that for the cross-reference product.

The Marketing Authorisation Holder has provided a commitment to update the Marketing Authorisation with a package leaflet in compliance with Article 59 of Council Directive 2001/83/EC and that the leaflet shall reflect the results of consultation with target patient groups, no later than 1st July 2008.

The approved labelling artwork complies with statutory requirements.

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 paracetamol, guafenesin, phenylephrine hydrochloride, and cetylpyridinium chloride is considered to have demonstrated the therapeutic value of the medicinal product. The risk: benefit is therefore considered to be positive.

THORNTON AND ROSS COLD & FLU FORMULA ORAL SOLUTION

(paracetamol, guafenesin, phenylephrine hydrochloride, cetylpyridinium chloride)

PL 00240/0144

STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the marketing authorisation application on 19th August 2005

2 Following standard checks and communication with the applicant the MHRA considered the application valid on 7th September 2005

3 Following assessment of the application the MHRA requested further information relating to the quality dossier on 27th January 2006 and 11th September 2007

4 The applicant responded to the MHRA's requests, providing further information for the quality sections on 29th August 2006 and 28th September 2007 respectively

5 The application was determined on 5th March 2008

SUMMARY OF PRODUCT CHARACTERISTICS

The UK Summary of Product Characteristics (SPC) for Thornton & Ross Cold & Flu Formula Oral Solution is as follows:

1 NAME OF THE MEDICINAL PRODUCT

Thornton & Ross Cold & Flu Formula Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 20ml dose contains:

Paracetamol 1000mg

Phenylephrine Hydrochloride 12.18mg

Guaifenesin 200mg

Cetylpyridinium Chloride 3.0mg

For full excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral Solution

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

For the short term symptomatic relief of the symptoms of colds and influenza, Including aches and pains, headache, nasal congestion, dry tickly sore throat and chesty coughs.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

For oral administration.

Adults and children over 12 years: One 20ml dose (four 5ml spoonfuls).

The dose must not be repeated more frequently than every four hours.

Maximum of 4 doses in any 24 hours.

Not recommended for children under 12 years of age except on medical advice.

4.3 CONTRAINDICATIONS

Patients with known hypersensitivity to paracetamol, phenylephrine hydrochloride, guaifenesin or cetylpyridinium chloride or any of the other ingredients.

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

Contraindicated during pregnancy.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Thornton & Ross Cold & Flu Formula is not suitable for long term use.

Paracetamol should be used with care in patients with severe renal or hepatic impairment. The hazard of overdose is greater than those with non –cirrhotic alcoholic liver disease.

Do not take with other cold or decongestant medicines or any other paracetamol-containing products.

Immediate medical advice should be sought in the event of an overdose even if you feel well, because of the risk of delayed serious liver damage.

Phenylephrine should be used with care in patients with hyperthyroidism, cardiovascular disease, diabetes mellitus, closed angle glaucoma, prostatic enlargement and hypertension.

Do not exceed the stated dose.

If symptoms persist consult your doctor.

Each dose contains approximately 3g of sorbitol. This product can be harmful in high doses, may be unsuitable for individuals with hereditary fructose intolerance, can cause headache, stomach upset and diarrhoea and may be harmful to people on a low potassium diet.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This product contains 15%w/v ethanol (equivalent to 19%v/v). Each dose contains up to 3g of ethanol. Caution! This medicine must not be taken by children, pregnant women and people suffering from liver disease, epilepsy, alcoholism, brain injury or disease. Reactions whilst driving or operating machinery may be lowered. This product may have an effect on other medicines.

Keep out the reach and sight of children.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone; and absorption reduced by cholestyramine. The anti-coagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect. Alcohol may potentiate the hepatotoxicity of paracetamol.

Phenylephrine may reduce the efficacy of beta-blocking drugs and antihypertensive drugs; the product is contraindicated in such circumstances.

With phenylephrine there is a possibility that an increased risk of arrhythmias may occur in patients receiving cardiac glycosides or tri-cyclic anti-depressants. Phenylephrine interacts with monoamine oxidase inhibitors; it should not therefore, be taken by patients receiving monoamine oxidase inhibitors or within 14 days of stopping such medication.

Guaifenesin may interfere with diagnostic measurements of urinary 5-hydroxyindoleacetic acid or vanillylmandelic acid.

4.6 PREGNANCY AND LACTATION

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

Phenylephrine should not be taken during pregnancy as it has been reported to cause foetal hypoxia. Excretion in breast milk is reported to be minimal.

Guaifenesin is considered safe for use in lactating women and at normal doses in pregnant women.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None

4.8 UNDESIRABLE EFFECTS

Undesirable effects with paracetamol are rare, however, hypersensitivity including skin rashes may occur. There have been a few reports of blood dyscrasias including thrombocytopenia and agranulocytosis after regular or excessive ingestion of paracetamol, and of acute pancreatitis after ingestion of above normal dosage.

Undesirable effects are rare with normal doses of phenylephrine, however it can cause the adverse effects typical of sympathomimetics including: hypertension, palpitations (tachycardia), headache, dizziness, vomiting, diarrhoea and insomnia.

Guaifenesin has occasionally been reported to cause gastrointestinal discomfort.

4.9 OVERDOSE

Early symptoms of paracetamol overdosage in the first 24 hours include pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning hepatic failure may progress to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported. Liver damage is possible in adults who have taken 10g or more of paracetamol. It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue.

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention.

Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within 1 hour. Plasma paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosing schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present serious hepatic dysfunction beyond 24 hours from ingestion should be discussed with the NPIS or a liver unit.

The principal features of phenylephrine overdosage are a rise in blood pressure and associated reflex bradycardia. A severe hypertensive response can be countered by administration of an alpha-antagonist and any reflex bradycardia by atropine (but preferably only after the pressure has been controlled by alpha-adrenergic blockade).

Very large doses of guaifenesin may cause nausea and vomiting.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

RO5X – Other cold combination preparations

Paracetamol has analgesic and antipyretic actions probably due to the inhibition of prostaglandin biosynthesis. It is effective against pain of mild to moderate severity, but is less successful against chronic pain.

Phenylephrine hydrochloride is a sympathomimetic agent with mainly direct effect on adrenergic receptors. It has predominantly alpha-adrenergic activity and is without significant stimulating effects on the central nervous system at usual doses. It may be given orally to relieve nasal congestion.

Guaifenesin is an expectorant which reduces the viscosity of tenacious sputum.

Cetylpyridinium Chloride is a cationic disinfectant with properties and uses similar to other cationic surfactants. These surfactants have bactericidal activity against Gram-positive and, at higher concentration against some Gram-negative organisms. Cetylpyridinium Chloride may be used in a variety of preparations for the local treatment of minor infections.

5.2 PHARMACOKINETIC PROPERTIES

Paracetamol is readily absorbed from the gastrointestinal tract and peak plasma concentrations usually occur 30 minutes to 2 hours after ingestion. Paracetamol is metabolised in the liver and largely excreted in the urine as sulphate and glucuronide conjugates. Less than 5% is excreted unchanged. The elimination half-life varies from about 1 to 4 hours.

Phenylephrine hydrochloride is irregularly absorbed after oral administration and undergoes first-pass metabolism by monoamine oxidase in the gut and liver, resulting in reduced bioavailability. Peak plasma concentrations are achieved in 1 to 2 hours. It is excreted in the urine mainly as the sulphate conjugate, with less than 20% as unchanged drug.

Guaifenesin is rapidly absorbed from the gastrointestinal tract. It is rapidly metabolised by oxidation to β-(2 methoxy-phenoxy) lactic acid, which is excreted in the urine.

Cetylpyridinium Chloride has only a local effect.

5.3 PRECLINICAL SAFETY DATA

There are no preclinical safety data on these active ingredients in the literature of relevance to the prescriber or to the recommended dosage and use of the product which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Liquid Maltitol (E965)
Sorbitol (E420)
Ethanol
Propylene Glycol (E1520)
Glycerol (E422)
Saccharin Sodium (E954)
Sodium Cyclamate (E952)
Acesulphame Potassium (E950)
Sodium Citrate (E331)
Anhydrous Citric Acid (E330)
Xanthan Gum (E415)
Levomenthol
Eucalyptus Oil
Quinoline yellow (E104)
Patent Blue V (E131)
Purified Water

6.2 INCOMPATIBILITIES

Not Applicable

6.3 SHELF LIFE

2 years

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Do not store above 25°C.

Keep the container in the outer carton.

Keep the container tightly closed.

6.5 NATURE AND CONTENTS OF CONTAINER

Clear type III glass bottle and polypropylene child resistant closure with aluminium foil film liner containing 160ml.

Clear PET bottle and polypropylene child resistant closure with aluminium foil film liner, containing 160ml

Graduated polypropylene measuring cup.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

No special requirements

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Limited
Linthwaite Laboratories
Huddersfield
HD7 5QH
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/0144

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

05/03/2008

10 DATE OF REVISION OF THE TEXT

05/03/2008

PATIENT INFORMATION LEAFLET

Thornton & Ross
COLD & FLU FORMULA
Oral Solution
PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription, for you to treat a mild illness without a doctor's help.
Nevertheless, you still need to use Thornton & Ross Cold & Flu Formula 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.*
- *You must see a doctor if your symptoms worsen or do not improve.*

In this leaflet:

Each 20ml dose contains Paracetamol 1000mg, Phenylephrine Hydrochloride 12.18mg, Guaifenesin 200mg and Cetylpyridinium Chloride 3.0mg as the active ingredients.

One of the active ingredients in this medicine is Guaifenesin. This is the new name for Guaiphenesin. The ingredient itself has not changed.

Also contains: Liquid Maltitol (E965), Sorbitol (E420), Ethanol, Propylene Glycol (E1520), Glycerol (E422), Saccharin Sodium (E954), Sodium Cyclamate (E952), Acesulphame Potassium (E950), Sodium Citrate (E331), Anhydrous Citric Acid (E330), Xanthan Gum (E415), Levomenthol, Eucalyptus Oil, Quinoline Yellow (E104), Patent Blue V (E131), Purified Water.

The Product Licence Holder and Manufacturer of your medicine is:
Thornton & Ross Ltd., Huddersfield, HD7 5QH, UK.

1. What Thornton & Ross Cold & Flu Formula is and what it is used for

Thornton & Ross Cold & Flu Formula is a green solution.
This medicine is available in bottles containing 160ml of liquid (8 doses).

This medicine provides short term relief of cold and flu symptoms, including aches and pains, headache, blocked nose and sinuses, dry tickly sore throat and chesty coughs.

Paracetamol is an analgesic (relieves pain). Phenylephrine Hydrochloride is a decongestant, it shrinks the blood vessels in the nose and sinuses which opens the airways helping you to breathe more easily. Guaifenesin is an expectorant which loosens phlegm and so will relieve chesty coughs. Cetylpyridinium Chloride is an antiseptic and anti-infective which will ease dry tickly sore throats.

2. Before you take Thornton & Ross Cold & Flu Formula

Do not take if:
- you are allergic to Paracetamol, Phenylephrine Hydrochloride, Guaifenesin, Cetylpyridinium Chloride or any of the ingredients detailed above, including menthol.
- you are pregnant.
- you have a rare hereditary intolerance to fructose.

Do not take with any other paracetamol-containing products.
This product contains a decongestant. Do not take with other products for the relief of colds, flu or congestion.

Check with your doctor before taking if:
- you suffer from liver or kidney problems, heart disease, diabetes, glaucoma, high blood pressure, prostate trouble or if you have an over active thyroid gland.
- you are breastfeeding.
- you are receiving any other medication especially any of the following drugs: Colestyramine, drugs used to prevent blood clotting (eg. warfarin), drugs for heart trouble, anti-depressants (including monoamine-oxidase inhibitors or MAOIs), Metoclopramide, Domperidone.

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Important information about some of the ingredients in this product

This product contains 19 vol% ethanol (alcohol), i.e. up to 3000mg per dose, equivalent to 76ml of beer or 32ml of wine per dose. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breastfeeding women, children and high-risk groups such as people with liver disease or epilepsy. The amount of alcohol in this medicinal product may alter the effects of other medicines, and may impair your ability to drive or use machines. This product also contains liquid maltitol and sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. Also contains propylene glycol, which may cause alcohol-like symptoms. Contains Azo colouring agents which may cause allergic reactions.

3. How to take Thornton & Ross Cold & Flu Formula

Shake well before each use.

Dose:
For oral use.
Adults, including the elderly and children over 12 years: Fill the measure cup to the 20ml mark and take one 20ml dose (four 5ml spoonfuls). Wipe the neck of the bottle clean and replace the cap securely, without over-tightening it.
The dose must not be repeated more frequently than every 4 hours and not more than four doses should be taken in any 24 hours.

Do not give to children under 12 years of age except on the advice of a doctor.

If you forget to take Thornton & Ross Cold & Flu Formula:
Do not take a double dose to make up for forgotten individual doses.

If symptoms persist consult your doctor.
DO NOT EXCEED THE STATED DOSE.

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

4. Possible side effects

Like all medicines, Thornton & Ross Cold & Flu Formula can have side effects.
Skin rashes or other allergic reactions may occur with Paracetamol, and rarely blood disorders have developed. With Phenylephrine there have been a few reports of dizziness, palpitations and high blood pressure, and an upset stomach may occur with Guaifenesin. This medicine may also cause headache or diarrhoea.

If you notice any side effects not mentioned in this leaflet, stop taking it and talk to your pharmacist or doctor.

5. Storing Thornton & Ross Cold & Flu Formula

Store safely out of the reach and sight of children.

Do not store above 25°C. In order to protect from light, keep container in the outer carton.
Keep the container tightly closed.

Do not use after the expiry date printed on the label and carton.
Do not use if any solids can be seen in the solution.

Leaflet Revised: September 2007

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LABELLING

Carton for bottle

Bottle label