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BENYLIN MUCUS COUGH & COLD ALL IN ONE RELIEF TABLETS
SUDAFED MUCUS RELIEF TRIPLE ACTION COLD & FLU TABLETS
PL 12063/0112

LAY SUMMARY

On 27th April 2011, the MHRA granted Wrafton Laboratories Limited a Marketing Authorisation (licence) for Benylin Mucus Cough & Cold All in One Relief Tablets/Sudafed Mucus Relief Triple Action Cold & Flu Tablets (PL 12063/0112).

Benylin Mucus Cough & Cold All in One Relief Tablets/Sudafed Mucus Relief Triple Action Cold & Flu Tablets contains:

- Paracetamol, which is a pain reliever (analgesic) and helps reduce your temperature when you have a fever.
- Guaifenesin which is an expectorant to help loosen phlegm.
- Phenylephrine which is a decongestant to reduce swelling in the passages of the nose to help you breathe more easily.

These tablets are used for the relief of symptoms of colds and flu, including aches and pains, headache, blocked nose, sore throat, chills and chesty coughs.

No new or unexpected safety concerns arose from this application and it was, therefore, judged that the benefits of taking Benylin Mucus Cough & Cold All in One Relief Tablets/Sudafed Mucus Relief Triple Action Cold & Flu Tablets outweigh the risks; hence a Marketing Authorisation has been granted.
BENYLIN MUCUS COUGH & COLD ALL IN ONE RELIEF TABLETS
SUDAFED MUCUS RELIEF TRIPLE ACTION COLD & FLU TABLETS
PL 12063/0112

SCIENTIFIC DISCUSSION

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Clinical assessment (including statistical assessment) .... Page 9
Overall conclusions and risk benefit assessment ......... Page 10
INTRODUCTION

The MHRA granted a Marketing Authorisation for the medicinal product Benylin Mucus Cough & Cold All in One Relief Tablets/Sudafed Mucus Relief Triple Action Cold & Flu Tablets (PL 12063/0112) to Wrafton Laboratories Limited on 27th April 2011. This medicine has a General Sales Licence (GSL) and is indicated for the relief of symptoms associated with colds and flu, including aches and pains, headache, blocked nose and sore throat, chills and chesty cough.

This application for Benylin Mucus Cough & Cold All in One Relief Tablets/Sudafed Mucus Relief Triple Action Cold & Flu Tablets is submitted according to Article 10c of Directive 2001/83/EC, cross-referring to Tesco Flu-Max All-In-One Chesty Cough & Cold Tablets, which was approved and licensed to Wrafton Laboratories Limited (PL 12063/0079) on 4th May 2010.

It is considered that the pharmacovigilance system as described by the applicant fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance together with the necessary means for notification of any adverse reaction suspected of occurring.

No new data were submitted nor were they necessary for this “simple” application, as the data are identical to that of the previously granted cross-reference product.
1. INTRODUCTION
This is a “simple” application for Benylin Mucus Cough & Cold All in One Relief Tablets/Sudafed Mucus Relief Triple Action Cold & Flu Tablets (PL 12063/0112) submitted under Article 10c of Directive 2001/83/EC. The proposed MA holder is Wrafton Laboratories Limited (T/A Perrigo), Braunton, Devon, EX33 2DL, United Kingdom.

This application cross-refers to Tesco Flu-Max All-In-One Chesty Cough & Cold Tablets, which was approved and licensed to Wrafton Laboratories Limited (PL 12063/0079) on 4th May 2010.

2. MARKETING AUTHORISATION APPLICATION FORM
2.1 NAME(S)
The proposed name of the product is Benylin Mucus Cough & Cold All in One Relief Tablets/Sudafed Mucus Relief Triple Action Cold & Flu Tablets. The product has been named in-line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes
Each tablet contains:
Paracetamol 250mg
Guaifenesin 100mg
Phenylephrine hydrochloride 5mg

The finished product is packaged in child resistant blisters composed of polyvinyl chloride (PVC) and aluminium

Pack sizes are 8 and 16 tablets.

The proposed shelf-life is 3 years with storage conditions ‘Do not store above 25°C’. This is consistent with the details registered for the cross-reference product.

2.3 Legal status
General Sales Licence (GSL).

2.4 Marketing authorisation holder/Contact Persons/Company
Wrafton Laboratories Limited (T/A Perrigo), Braunton, Devon, EX33 2DL, United Kingdom.
The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers
The manufacturing sites are consistent with those registered for the cross-reference product and evidence of GMP compliance has been provided.

2.6 Qualitative and quantitative composition
The composition is consistent with the details registered for the cross-reference product.

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

2.8 Finished product/shelf-life specification
The finished product specification is in-line with the details registered for the cross-reference product.

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

2.10 TSE Compliance
None of the excipients used contain material of animal or human origin.
This information is consistent with the cross-reference product.

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts’ CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

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 summary 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.

No user testing results have been submitted and none are required, because the PIL is identical to that of the currently granted reference product, Tesco Flu-Max All-In-One Chesty Cough & Cold Tablets (PL 12063/0079).
Labelling
The artwork is comparable to the artwork registered for the cross-reference product and complies with statutory requirements. In-line with current legislation, the applicant has included the name of the product in Braille on the packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS
The data submitted with the application are acceptable. The grant of a Marketing Authorisation is recommended.
NON-CLINICAL ASSESSMENT

No new non-clinical data have been supplied with this application and none are required for applications of this type.

A satisfactory justification has been provided for non-submission of an Environmental Risk Assessment.
CLINICAL ASSESSMENT

No new clinical data have been supplied with this application and none are required for applications of this type.
OVERALL CONCLUSION AND RISK BENEFIT ASSESSMENT

QUALITY
The data for this application are consistent with those previously approved for the cross-reference product and, as such, has been judged to be satisfactory.

NON-CLINICAL
No new non-clinical data were submitted and none are required for applications of this type.

EFFICACY
This application is identical to the previously granted application, Tesco Flu-Max All-In-One Chesty Cough & Cold Tablets, which was approved and licensed to Wrafton Laboratories Limited (PL 12063/0079) on 4th May 2010.

No new or unexpected safety concerns arise from this application.

The SmPC, 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 non-clinical or clinical safety concerns have been identified. The applicant’s product is identical to the cross-reference product. Extensive clinical experience with paracetamol, guaifenesin and phenylephrine hydrochloride is considered to have demonstrated the therapeutic value of the compounds. The risk:benefit is, therefore, considered to be positive.
STEPS TAKEN FOR ASSESMENT

<table>
<thead>
<tr>
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<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>The MHRA received the Marketing Authorisation Application on 10\textsuperscript{th} May 2010.</td>
</tr>
<tr>
<td>2</td>
<td>Following standard checks and communication with the applicant the MHRA considered the application valid on 14\textsuperscript{th} June 2010.</td>
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<td>3</td>
<td>Following assessment of the application further information was requested regarding the quality section of the dossier on 28\textsuperscript{th} June 2010.</td>
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<tr>
<td>4</td>
<td>The applicant responded to the MHRA’s requests, providing further information on 13\textsuperscript{th} July 2010 for the quality section.</td>
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<tr>
<td>5</td>
<td>The application was determined on 27\textsuperscript{th} April 2011.</td>
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</table>
BENYLIN MUCUS COUGH & COLD ALL IN ONE RELIEF TABLETS
SUDAFED MUCUS RELIEF TRIPLE ACTION COLD & FLU TABLETS
PL 12063/0112

STEPS TAKEN AFTER ASSESSMENT

<table>
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<tr>
<th>Date submitted</th>
<th>Application type</th>
<th>Scope</th>
<th>Outcome</th>
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SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
Benylin Mucus Cough & Cold All in One Relief Tablets
Sudafed Mucus Relief Triple Action Cold & Flu Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>mg/Tablet</th>
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</thead>
<tbody>
<tr>
<td>Paracetamol</td>
<td>250</td>
</tr>
<tr>
<td>Guaifenesin</td>
<td>100</td>
</tr>
<tr>
<td>Phenylephrine Hydrochloride</td>
<td>5</td>
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</tbody>
</table>

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
Film-coated tablet
White capsule shaped tablet, embossed with “PGP”, free from specks and blemishes.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS
For the relief of symptoms associated with colds and flu, including aches and pains, headache, blocked nose and sore throat, chills and chesty cough.

4.2 POSOLOGY AND METHOD OF ADMINISTRATION
For oral use. Take tablets with water. Swallow whole, do not chew.

Adults, the Elderly and children aged 12 years and over:
Two tablets. Repeat every four hours as required. Do not take more than 8 tablets (4 doses) in any 24 hour period.
Do not give to children under 12 years, except on medical advice.

Do not exceed the stated dose.

4.3 CONTRAINDICATIONS
Hypersensitivity to paracetamol or any of the other ingredients.

Hypertension, hyperthyroidism, diabetes, serious heart disease or those patients receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors.

Use in patients with glaucoma or urinary retention.

Use in patients who are currently receiving other sympathomimetic drugs.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE
The physician or pharmacist should check that sympathomimetic containing preparations are not simultaneously administered by several routes i.e. orally and topically (nasal, aural and eye preparations).

Care is advised in the administration of paracetamol to patients with severe renal or hepatic impairment. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.

Use with caution in patients with circulatory disorders such as Raynaud’s Phenomenon.

Patients with prostatic hypertrophy may have increased difficulty with micturition.

Sympathomimetic-containing products may act as cerebral stimulants giving rise to insomnia, nervousness, hyperpyrexia, tremor and epileptiform convulsions.

Long term use of the product is not recommended.
Do not exceed the recommended dose.
If symptoms persist consult your doctor.
Keep all medicines out of the reach and sight of children.

Special label warnings
Contains paracetamol. Do not take with any other paracetamol-containing products. Immediate medical advice should be sought in the event of an overdose, even if you feel well.

Do not take with any other flu, cold or decongestant products.

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
PARACETAMOL
The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by colestyramine.

The anticoagulant 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.

Drugs which induce hepatic microsomal enzymes, such as alcohol, barbiturates, monoamine oxidase inhibitors and tricyclic antidepressants, may increase the hepatotoxicity of paracetamol particularly after overdosage. Contraindicated in patients currently receiving or within two weeks of stopping therapy with monoamine oxidase inhibitors because of a risk of hypertensive crisis.

PHENYLEPHRINE HYDROCHLORIDE
Phenylephrine may adversely interact with other sympathomimetics, vasodilators and beta blockers.

Sympathomimetic-containing products should be used with great care in patients suffering from angina and in patients receiving phenothiazines or tricyclic antidepressants.

Sympathomimetic-containing products should be used in caution in patients receiving digitalis, beta-adrenergic blockers, guanethidine, reserpine, methylidopa or anti-hypertensive agents

Concurrent use with halogentated anaesthetic agents such as chloroform, cyclopropane, halothane, enflurane or isoflurane may provoke or worsen ventricular arrhythmias.

4.6 PREGNANCY AND LACTATION
PARACETAMOL
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.

GUAIFENESIN
The safety of guaifenesin in pregnancy and lactation has not been fully established but this constituent is not thought to be hazardous. However the product should only be used in pregnancy when considered essential by the doctor.

PHENYLEPHRINE HYDROCHLORIDE
Due to the vasoconstrictive properties of Phenylephrine, the product should be used with caution in patients with a history of pre-eclampsia. Phenylephrine may reduce placental perfusion and the product should be used in pregnancy only if the benefits outweigh this risk. There is no information on use in lactation.
4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES
None known

4.8 UNDESIRABLE EFFECTS
The active ingredients are usually well tolerated in normal use.

PARACETAMOL
Adverse effects of paracetamol are rare but hypersensitivity including skin rashes may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol. The active ingredients are usually well tolerated in normal use.

GUAIFENESIN
Gastrointestinal discomfort has occasionally been reported with guaifenesin.

PHENYLEPHRINE HYDROCHLORIDE
Phenylephrine Hydrochloride may elevate blood pressure with headache, vomiting and rarely palpitations, tachycardia or reflex bradycardia, tingling and coolness of the skin. There have been rare reports of allergic reactions.

4.9 OVERDOSE
PARACETAMOL
Liver damage is possible in adults who have taken 10 g or more of paracetamol. Ingestion of 5 g or more of paracetamol may lead to liver damage if the patient has risk factors (see below).

Risk Factors
If the patient
a) is on long term treatment with carbamazepine, phenobarbital, phenytoin, primidone, rifampicin, St John’s Wort or other drugs that induce liver enzymes.

or

b) Regularly consumes ethanol in excess of recommended amounts.

or

c) Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms
Symptoms of paracetamol overdose in the first 24 hours are 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, haemorrhage, hypoglycaemia, cerebral oedema, and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Management
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 British National Formulary (BNF) overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within one hour. Plasma paracetamol concentration should be measured at four 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 eight 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 dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside
hospital. Management of patients who present with serious hepatic dysfunction beyond 24 hours from ingestion should be discussed with the National Poisons Information Service (NPIS) or a liver unit.

**GUAIFENESIN**
Gastrointestinal discomfort has occasionally been reported with Guaifenesin.

**PHENYLEPHRINE HYDROCHLORIDE**
Phenylephrine hydrochloride may elevate blood pressure with headache, vomiting and rarely palpitations, tachycardia or reflex bradycardia, tingling and coolness of the skin. There have been rare reports of allergic reactions.

### 5 PHARMACOLOGICAL PROPERTIES
#### 5.1 PHARMACODYNAMIC PROPERTIES
Pharmacotherapeutic Group: Other analgesics and antipyretics & Other cold combination preparations

ATC code: N02B E51

Paracetamol is an analgesic and antipyretic.
Guaifenesin is an expectorant.
Phenylephrine Hydrochloride is a sympathomimetic decongestant.

The active ingredients are not known to cause sedation.

#### 5.2 PHARMACOKINETIC PROPERTIES
Paracetamol is rapidly absorbed from the gastrointestinal tract. It is metabolised in the liver and excreted in the urine, mainly as the glucuronide and sulphate conjugates.

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

Phenylephrine hydrochloride is irregularly absorbed from the gastrointestinal tract and undergoes first-pass metabolism by monoamine oxidase in the gut and liver; orally administered phenylephrine thus has reduced bioavailability. It is excreted in the urine almost entirely as the sulphate conjugate.

#### 5.3 PRECLINICAL SAFETY DATA
Preclinical safety data on these active ingredients in the literature have not revealed any pertinent and conclusive findings which are of relevance to the recommended dosage and use in the product and which have not already been mentioned elsewhere in this Summary.

### 6 PHARMACEUTICAL PARTICULARS
#### 6.1 LIST OF EXCIPIENTS
**Core:**
- Microcrystalline cellulose
- Stearic acid
- Povidone

**Film Coat:**
- Hypromellose
- Polyethylene glycol

#### 6.2 INCOMPATIBILITIES
None known

#### 6.3 SHELF LIFE
3 years.

#### 6.4 SPECIAL PRECAUTIONS FOR STORAGE
Do not store above 25°C.
6.5 NATURE AND CONTENTS OF CONTAINER
Child Resistant PVC/Al blister.
Pack sizes: 8 and 16 tablets.

6.6 SPECIAL PRECAUTIONS FOR DISPOSAL
None

7 MARKETING AUTHORISATION HOLDER
Wrafton Laboratories Limited (T/A Perrigo)
Braunton
Devon
EX33 2DL

8 MARKETING AUTHORISATION NUMBER(S)
PL 12063/0112

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
27/04/2011

10 DATE OF REVISION OF THE TEXT
27/04/2011
Paracetamol, Guaifenesin & Phenylephrine

Read all of this leaflet carefully before you take this medicine because it contains important information you need to know. This medicine is available without prescription, however, you still need to use this product carefully to get the best results from it. Keep this leaflet as you may need to read it again. Ask your pharmacist if you need more information or advice.

1. What is this medicine and what is it used for?
This medicine contains:
- paracetamol which is a pain reliever (analgesic) and helps reduce your temperature when you have a fever
- guaifenesin which is an expectorant to help loosen phlegm
- phenylephrine which is a decongestant to reduce swelling in the passages of the nose to help you breathe more easily.

These tablets are used for the relief of symptoms of colds and flu, including aches and pains, headache, blocked nose, sore throat, chills and chesty coughs.

2. Is this medicine suitable for you?
Do not take this medicine if you:
- are allergic to paracetamol, guaifenesin, phenylephrine or any of the other ingredients
- have a serious heart condition
- have high blood pressure (hypertension)
- have diabetes
- have an overactive thyroid
- have glaucoma
- have difficulty passing urine
- are taking antidepressant drugs called monoamine oxidase inhibitors (MAOIs), or have taken them within the last 14 days - these are medicines such as phenelzine and isocarboxazid
- are currently taking other decongestant drugs or stimulants (e.g. ephedrine, amphetamines and xylometazoline).

Please see your doctor or pharmacist before taking this medicine if you:
- are pregnant or breast-feeding
- suffer from kidney or liver problems, including alcoholic liver disease
- have circulatory disorders such as a condition called Raynaud's Phenomenon, which results from poor circulation in the fingers and toes
- have angina
- have an enlarged prostate gland, as this may cause more difficulty in passing urine.

If you are taking any of the following medicines please see your doctor:
- medicines to treat high cholesterol levels which reduce the amount of fat in the blood such as colestyramine
- medicines to control feeling sick or being sick such as metoclopramide or domperidone
- medicines called anti-coagulants, which are used to thin the blood such as warfarin or other coumarins - you may take occasional doses of paracetamol but should consult your doctor if you need to take it on a regular basis
- barbiturates (for epilepsy or to help you sleep), such as phenobarbitones
- tricyclic antidepressants such as imipramine, amitriptyline
- medicines to treat heart or circulatory problems, or to lower blood pressure, (e.g. digoxin, guanethidine, reserpine, methyldopa)
- beta blockers (e.g. atenolol) or vasodilators (e.g. hydralazine)
- phenothiazines used as sedatives (e.g. chlorpromazine, pericyazine and fluphenazine)
- if you are going to have a general anaesthetic as this may cause changes in heart rhythm. Please turn over ▶
2. Is this medicine suitable for you? (Continued)
Contains paracetamol.
Do not take with any other paracetamol-containing products.
Other important information:
Do not drink alcohol (beer, wine, spirits etc) while taking this product.
If you are taking medication, or are under medical care, consult your doctor before using this medicine.
Long term use of this product is not recommended.

3. How to take this medicine
Swallow the tablets whole with water. Do not chew.
Adults, the elderly and children 12 years and over: 2 tablets every 4 hours, as required. Do not take more than 8 tablets (4 doses) in any 24 hour period.
Do not give to children under 12 years.
Do not exceed the stated dose. If your symptoms persist or worsen, you must see a doctor or pharmacist.
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. Go to your nearest hospital casualty department. Take your medicine and this leaflet with you.

4. Possible side-effects
Most people do not have any side-effects while taking this medicine. However, if you experience any of the following side-effects, or anything else unusual happens, stop taking the medicine immediately, and see your doctor or pharmacist.
Rare side effects are:
- allergic reactions such as skin rash
- stomach upsets
- tingling or coolness of the skin
- a faster or slower heart beat
- difficulty sleeping (insomnia)
- nervousness, tremors or convulsions
- a rise in body temperature
- a rise in blood pressure with headache, vomiting (being sick) and irregular heartbeat (palpitations).
More rarely, the following side effects can happen:
- you may become more prone to bleeding, bruising, fever and infections such as sore throat and ulcers, due to changes in your blood.

5. How to store your medicine
Keep all medicines out of the reach and sight of children.
Do not use this medicine after the expiry date which is stated on the carton and blister foil.
The expiry date refers to the last day of the month.
Do not store above 25°C.

6. What is in this medicine?
Each white, capsule-shaped tablet contains the active ingredients: paracetamol 250 mg, guaifenesin 100 mg and phenylephrine hydrochloride 5 mg.
The other ingredients are: microcrystalline cellulose, stearic acid, povidone, hypromellose and polyethylene glycol.
This product is available in a pack size of 16 tablets.

7. Who makes this medicine?
The Marketing Authorisation holder and manufacturer is Perrigo, Braunton, Devon, EX33 2DL, UK.
The distributor is McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.
Text revised: March 2011.
PL 12063/0112
10-0696 2734192
Read all of this leaflet carefully before you take this medicine because it contains important information you need to know. This medicine is available without prescription, however, you still need to use this product carefully to get the best results from it. Keep this leaflet as you may need to read it again. Ask your pharmacist if you need more information or advice.

1. What is this medicine and what is it used for?

This medicine contains:

- **paracetamol** which is a pain reliever (analgesic) and helps reduce your temperature when you have a fever
- **guaifenesin** which is an expectorant to help loosen phlegm
- **phenylephrine** which is a decongestant to reduce swelling in the passages of the nose to help you breathe more easily.

These tablets are used for the relief of symptoms of colds and flu, including aches and pains, headache, blocked nose, sore throat, chills and chesty coughs.

2. Is this medicine suitable for you?

Do not take this medicine if you:

- are allergic to paracetamol, guaifenesin, phenylephrine or any of the other ingredients
- have a serious heart condition
- have high blood pressure (hypertension)
- have diabetes
- have an overactive thyroid
- have glaucoma
- have difficulty passing urine
- are taking antidepressant drugs called monoamine oxidase inhibitors (MAOI’s), or have taken them within the last 14 days - these are medicines such as phenelzine and isocarboxazid

- are currently taking other decongestant drugs or stimulants (e.g. ephedrine, amphetamines and xylometazoline).

Please see your doctor or pharmacist before taking this medicine if you:

- are pregnant or breast-feeding
- suffer from kidney or liver problems, including alcoholic liver disease
- have circulatory disorders such as a condition called Raynaud’s Phenomenon, which results from poor circulation in the fingers and toes
- have angina
- have an enlarged prostate gland, as this may cause more difficulty in passing urine.

If you are taking any of the following medicines please see your doctor:

- medicines to treat high cholesterol levels which reduce the amount of fat in the blood such as colestyramine
- medicines to control feeling sick or being sick such as metoclopramide or domperidone
- medicines called anti-coagulants, which are used to thin the blood such as warfarin or other coumarins - you may take occasional doses of paracetamol but should consult your doctor if you need to take it on a regular basis
- barbiturates (for epilepsy or to help you sleep), such as phenobarbitones
- tricyclic antidepressants such as imipramine, amitriptyline
- medicines to treat heart or circulatory problems, or to lower blood pressure, (e.g. digoxin, guanethidine, reserpine, methyldopa)
- beta blockers (e.g. atenolol) or vasodilators (e.g. hydralazine)
- phenothiazines used as sedatives (e.g. chlorpromazine, pericyazine and fluphenazine)
- if you are going to have a general anaesthetic as this may cause changes in heart rhythm.

*Please turn over*
2. Is this medicine suitable for you? (Continued)

Contains paracetamol.

Do not take with any other paracetamol-containing products.

Other important information:
Do not drink alcohol (beer, wine, spirits etc) while taking this product.
If you are taking medication, or are under medical care, consult your doctor before using this medicine.

Long term use of this product is not recommended.

3. How to take this medicine

Swallow the tablets whole with water. Do not chew.

Adults, the elderly and children 12 years and over:
2 tablets every 4 hours, as required. Do not take more than 8 tablets (4 doses) in any 24 hour period.

Do not give to children under 12 years.
Do not exceed the stated dose. If your symptoms persist or worsen, you must see a doctor or pharmacist.

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. Go to your nearest hospital casualty department. Take your medicine and this leaflet with you.

4. Possible side-effects

Most people do not have any side-effects while taking this medicine. However, if you experience any of the following side-effects, or anything else unusual happens, stop taking the medicine immediately, and see your doctor or pharmacist.

Rare side effects are:
- allergic reactions such as skin rash
- stomach upset
- tingling or coolness of the skin
- a faster or slower heart beat
- difficulty sleeping (insomnia)
- nervousness, tremors or convulsions
- a rise in body temperature
- a rise in blood pressure with headache, vomiting (being sick) and irregular heartbeat (palpitations).

More rarely, the following side effects can happen:
- you may become more prone to bleeding, bruising, fever and infections such as sore throat and ulcers, due to changes in your blood.

5. How to store your medicine

Keep all medicines out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the carton and blister foil.
The expiry date refers to the last day of the month.
Do not store above 25°C.

6. What is in this medicine?

Each white, capsule-shaped tablet contains the active ingredients: paracetamol 250 mg, guaifenesin 100 mg and phenylephrine hydrochloride 5 mg.

The other ingredients are: microcrystalline cellulose, stearic acid, povidone, hypromellose and polyethylene glycol.

This product is available in a pack size of 16 tablets.

7. Who makes this medicine?

The Marketing Authorisation holder and manufacturer is Perrigo, Braunton, Devon, EX33 2DL, UK.
The distributor is McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

Text revised: March 2011.
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Benylin Mucus Cough & Cold All in One Relief Tablets
Sudafed Mucus Relief Triple Action Cold & Flu Tablets

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