Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Benylin Phlegm Cough plus Decongestant Syrup
Guaifenesin 100mg/5ml
Pseudoephedrine Hydrochloride 30mg/5ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of syrup contains 100 mg of Guaifenesin and 30 mg of Pseudoephedrine Hydrochloride.

Excipients:
Also includes sucrose 3g per 5ml; Sunset Yellow (E110) 0.25mg per 5ml; Ponceau 4R (E124) 0.25mg per 5ml; Methyl hydroxybenzoate (E218) 5.0mg per 5ml, Propyl hydroxybenzoate (E216) 0.5mg per 5ml and ethanol (96%) 0.25ml per 5ml.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Syrup
A clear orange-red, cherry-flavoured syrup.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Benylin Phlegm Cough plus Decongestant Syrup is indicated for the symptomatic relief of upper respiratory tract disorders accompanied by productive cough which benefits from a combination of a nasal decongestant and an expectorant.

4.2 Posology and method of administration

Adults and children over 12 years:
10 ml every 4-6 hours, up to four times a day

Children under 12 years:
Not recommended (see section 4.3)

Older people:
There have been no specific studies of Benylin Phlegm Cough plus Decongestant Syrup in the elderly. Experience has indicated that normal adult dosage is appropriate, although it may be advisable to monitor renal and/or hepatic function. If there is serious impairment then caution should be exercised.

Method of Administration
For oral use

4.3 Contraindications

Benylin Phlegm Cough plus Decongestant Syrup is contra-indicated in individuals who have previously exhibited intolerance to Pseudoephedrine, Guaifenesin or any of its excipients (See Section 4.4 for warnings on excipients and section 6.1 for list of excipients).

Benylin Phlegm Cough plus Decongestant Syrup is contra-indicated in patients who are taking or have taken monoamine oxidase inhibitors within the preceding two weeks. The concomitant use of pseudoephedrine and this type of product may cause a rise in blood pressure or hypertensive crisis (See Section 4.5).

Benylin Phlegm Cough plus Decongestant Syrup is contra-indicated in patients with severe hypertension or severe coronary artery disease.

The antibacterial agent furazolidone is known to cause a dose-related inhibition of monoamine oxidase. Although there are no reports of hypertensive crises caused by the concurrent administration of Benylin Phlegm Cough plus Decongestant Syrup and furazolidone, they should not be taken together.

Benylin Phlegm Cough plus Decongestant Syrup is contraindicated for use in children under 12 years.

4.4 Special warnings and precautions for use

Although pseudoephedrine has virtually no pressor effects in normotensive patients, Benylin Phlegm Cough plus Decongestant Syrup should be used with caution in patients taking antihypertensive agents, tricyclic antidepressants or other sympathomimetic agents, such as decongestants, appetite suppressants and amphetamine-like psychostimulants. The effects of a single dose of Benylin Phlegm Cough plus Decongestant Syrup on the blood pressure of these patients should be observed before recommending repeated or unsupervised treatment.

Patients with the following conditions should be advised to consult a physician before using this product: pre-existing cardiovascular disease in particular those with coronary heart disease and hypertension; diabetes; thyroid disease; increased intra-ocular pressure, glaucoma; difficulty in urination due to enlargement of the prostate; a respiratory condition such as emphysema, chronic bronchitis or acute or chronic bronchial asthma, [see section 4.3 and section 4.5].

There have been no specific studies of Benylin Phlegm Cough plus Decongestant Syrup in patients with hepatic and/or renal dysfunction. Caution should be exercised in the presence of severe renal or hepatic impairment.

Benylin Phlegm Cough plus Decongestant Syrup should not be used for persistent or chronic cough such as occurs with smoking, asthma or emphysema or where cough is accompanied by excessive secretions unless directed by a physician.

Not more than 4 doses should be given in any 24 hours. Do not exceed the stated dose.

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

This product contains 5% v/v ethanol (alcohol), i.e. up to 190 mg per 5ml, equivalent to approximately 5 ml beer, 2 ml wine per 5 ml dose. This can be harmful for those suffering from alcoholism. The ethanol content should be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver or kidney disease or epilepsy.

If cough tends to recur, or is accompanied by a fever, rash, or persistent headache, a physician should be consulted.

This product contains Ponceau 4R (E124) red colouring and sunset yellow (E110) which may cause allergic reactions.

This product contains Methyl Hydroxybenzoate (E 218) and Propyl Hydroxybenzoate (E 216) which may cause allergic reactions (Possibly delayed)

Do not take with any other cough and cold medicine.

If symptoms persist or get worse, or if new symptoms occur, patients should stop use and consult a physician.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of Benylin Phlegm Cough plus Decongestant Syrup with other sympathomimetic agents such as decongestants, tricyclic antidepressants, appetite suppressants and amphetamine-like psychostimulants or with monoamine oxidase inhibitors, which interfere with the catabolism of sympathomimetic amines, may cause a rise in blood pressure. (See section 4.8)

Because of its pseudoephedrine content, Benylin Phlegm Cough plus Decongestant Syrup may partially reverse the hypotensive action of drugs which interfere with sympathetic activity including bretylium, bethanidine, guanethidine, debrisoquine, methyldopa, alpha- and beta-adrenergic blocking agents.

Pseudoephedrine exerts its vasoconstricting properties by stimulating adrenergic receptors and displacing norepinephrine from neuronal storage sites. Since MAOIs impede the metabolism of sympathomimetic amines and increase the store of releasable norepinephrine in adrenergic nervous tissue, MAOIs may potentiate the pressor effect of pseudoephedrine. Acute hypertensive crises have been reported in the medical literature with the concomitant use of MAOIs and sympathomimetic amines.

4.6 Fertility, pregnancy and lactation

This product should not be used during pregnancy or lactation unless the potential benefit of treatment to the mother outweighs the possible risks to the developing foetus or nursing infant.

Pregnancy
Although pseudoephedrine and guaifenesin have been in widespread use for many years without apparent ill consequence, there are no specific data on their use during preganancy.

Breast-feeding
Pseudoephedrine distributes into and is concentrated in breast milk. Up to 0.7% of a single 60 mg dose of pseudoephedrine may be distributed into breast milk over 24 hours. Pseudoephedrine concentrations in milk are from 2 to 3 fold higher than those in plasma. This milk/plasma drug concentration profile suggests low protein binding, although no plasma protein binding data in humans are available. Data from a study of lactating mothers taking 60 mg pseudoephedrine every 6 hours suggests that from 2.2 to 6.7% of the maximum daily dose (240 mg) may be available to the infant from a breastfeeding mother.

Guaifenesin is excreted in breast milk in small amounts with no effect on the infant.

4.7 Effects on ability to drive and use machines

It is not known if this product has an effect on the ability to drive or operate machinery.

4.8 Undesirable effects

Placebo-controlled studies with sufficient adverse event data were not available for the combination of guaifenesin and pseudoephedrine.

Adverse drug reactions identified during clinical trials and post-marketing experience with guaifenesin or pseudoephedrine or combination are listed below by System Organ Class (SOC).

The frequencies are defined according to the following convention:
Very common ≥1/10
Common ≥1/100 and < 1/10
Uncommon ≥1/1,000 and <1/100
Rare ≥1/10,000 and <1/1,000
Very rare <1/10,000
Not known (cannot be estimated from the available data).

ADRs are presented by frequency category based on 1) incidence in adequately designed clinical trials or epidemiology studies, if available, or 2) when incidence cannot be estimated, frequency category is listed as 'Not known'

System Organ Class (SOC)	Frequency	Adverse Drug Reaction (Preferred Term)
Immune System Disorders	Not Known Not Known	Hypersensitivity[1,2] Angioedema[3]
Psychiatric Disorders	Common Common Rare Not Known Not Known Not Known Not Known Not Known	Insomnia[†,2] Nervousness[††,2] Hallucinations Agitation[3] Anxiety[2] Euphoric mood[2] Sleep disorder Restlessness
Nervous System Disorders	Common Not Known Not Known	Dizziness[†,2] Headache[2] Psychomotor hyperactivity (in the paediatric population) [2]
Cardiac Disorders	Not Known Not Known Not Known	Arrhythmia[2] Palpitations[2] Tachycardia[2]
Gastrointestinal Disorders	Common Common Not Known Not Known Not Known	Dry mouth[†2] Nausea[†1,2] Abdominal pain[1,3] Diarrhoea[1] Vomiting[1]
Skin and Subcutaneous Tissue Disorders	Not Known Not Known Not Known	Pruritus[1,3] Rash[1] Urticaria[1,3]
Renal and Urinary Disorders	Not Known Not Known	Dysuria[2] Urinary Retention[2]
General Disorders and Administration Site Conditions	Not Known	Feeling Jittery[2]
Investigations	Not Known	Blood pressure increased[2]

† Adverse events reported by ≥1% of subjects in randomised, placebo-controlled trials with single-ingredient pseudoephedrine.

[1] ADRs associated with guaifenesin

[2] ADRs associated with pseudoephedrine

[3] Additional ADRs attributed to guaifenesin & pseudoephedrine in combination

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

Symptoms and signs

Symptoms
The effects of acute toxicity from Benylin Phlegm Cough plus Decongestant Syrup may include gastro-intestinal discomfort, nausea, vomiting, irritability, restlessness, tremor, convulsions, palpitations, hypertension, and difficulty with micturition.

Guaifenesin
Somnolence (very rare) may be associated with guaifenesin overdose.
When taken in excess, guaifenesin may cause renal calculi.

Pseudoephedrine
Overdosage may result in nausea, vomiting, sympathomimetic symptoms including central nervous system stimulation, insomnia, tremor, mydriasis, anxiety, agitation, hallucinations, seizures, palpitations, tachycardia, hypertension, and reflex bradycardia.

Other effects may include dysrhythmias, hypertensive crisis, intracerebral haemorrhage, myocardial infarction, psychoses, rhabdomyolysis, hypokalaemia, and ischemic bowel infarction.
Drowsiness has been reported with overdose in children

Management
Necessary measures should be taken to maintain and support respiration and control convulsions. Gastric lavage should be performed if indicated. Catheterisation of the bladder may be necessary. If desired, the elimination of pseudoephedrine can be accelerated by acid diuresis or by dialysis.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code: R01BA52 (Pseudoephedrine, combinations)

Pseudoephedrine has direct and indirect sympathomimetic activity and is an orally effective upper respiratory decongestant. Pseudoephedrine is substantially less potent than ephedfine in producing both tachycardia and elevation of systolic blood pressure and considerably less potent in causing stimulation of the central nervous system.
Guaifenesin has an expectorant action. It is thought to reduce sputum viscosity by increasing the volume and water content of the bronchial secretion, thereby facilitating the expectoration of sputum.

Pseudoephedrine produces its decongestant effect within 30 minutes, persisting for a least 4 hours. Guaifenesin produces its expectorant action within 24 hours.

5.2 Pharmacokinetic properties

In healthy adult volunteers, the administration of 60 mg pseudoephedrine resulted in a peak plasma concentration (Cmax) of approximately 180 ng/ml occurring at about 2 hours (Tmax) after drug administration. The plasma half-life was approximately 5.5 hours (urine pH maintained between 5.0-7.0). The plasma half-life of pseudoephedrine is markedly decreased by acidification of urine and increased by alkalinisation.

After the administration of 600 mg guaifenesin in healthy adult volunteers the Cmax was approximately 1.4 microgram/ml with Tmax about 15 minutes after drug administration. Guaifenesin had a plasma half-life of approximately 1 hour and was not detectable in the blood after 8 hours.

5.3 Preclinical safety data

Mutagenicity
The results of a wide range of tests indicate that pseudoephedrine does not pose a mutagenic risk to man.

Carcinogenicity
There is insufficient information available to determine whether pseudoephedrine or guaifenesin have carcinogenic potential.

Teratogenicity
Systemic administration of pseudoephedrine up to 50 times the human daily dosage in rats and up to 35 times the human daily dosage in rabbits, did not produce teratogenic effects.

There is insufficient information available to determine whether guaifenesin has teratogenic potential.

Fertility
Systemic administration of pseudoephedrine in rats, up to 7 times the human daily dosage in females and 35 times the human daily dosage in males, did not impair fertility or alter foetal morphological development and survival.

There is insufficient information to determine whether guaifenesin has the potential to impair fertility.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Glycerol
Methyl hydroxybenzoate (E218)
Propyl hydroxybenzoate (E216)
Ethanol
Levomenthol
Ponceau 4R (E124)
Sunset Yellow (E110)
Flavour, Wild Cherry
(Contains ethanol)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C. Keep container in the outer carton in order to protect from light.
Do not refrigerate.

6.5 Nature and contents of container

100 ml amber glass bottles fitted with metal roll on closures or HDPE screw caps fitted with saran or steran (PVDC)-faced wads or a 3 piece plastic child resistant, tamper evident closure fitted with a PVDC faced wad or polyethylene/expanded polyethylene laminated wad.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

McNeil Healthcare (Ireland) Ltd.
Airton Road
Tallaght
Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA0823/043/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Last date of authorisation: 07 April 2007

10 DATE OF REVISION OF THE TEXT

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