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

Excipients with known effect: Each 5ml contains:

Sucrose 3g
Sunset yellow (E110) 0.25mg
Ponceau 4R (E124) 0.25mg
Methyl hydroxybenzoate (E218) 5.0mg
Propyl hydroxybenzoate (E216) 0.5mg
Ethanol 188mg
Benzyl alcohol 0.02mg

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

Posology

Adults and children over 12 years:

10 ml every 4-6 hours, up to four times a day

Children under 12 years:

This medicine is contra-indicated in children under 12 years of age (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.

Hepatic Dysfunction:
Caution should be exercised when administering Benylin Phlegm Cough plus Decongestant to patients with severe hepatic impairment.

Renal Dysfunction:
Caution should be exercised when administering Benylin Phlegm Cough plus Decongestant to patients with mild to moderate renal impairment.

Method of Administration
For oral use

4.3 Contraindications

Benylin Phlegm Cough plus Decongestant Syrup is contra-indicated in individuals with known hypersensitivity to Pseudoephedrine, Guaifenesin or to any of the excipients listed in section 6.1.

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 and/or hypertensive crisis (See Section 4.5).

Benylin Phlegm Cough plus Decongestant Syrup is contra-indicated in patients with cardiovascular disease including hypertension and in those who are taking beta-blockers (see section 4.5).

Benylin Phlegm Cough plus Decongestant Syrup is contra-indicated in individuals who have diabetes mellitus, phaeochromocytoma, hyperthyroidism, closed angle glaucoma or severe renal impairment.

Benylin Phlegm Cough plus Decongestant Syrup is contra-indicated in individuals who are currently receiving other sympathomimetic decongestants.

This medicine is contraindicated in patients at risk of developing respiratory failure.

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

4.4 Special warnings and precautions for use

If any of the following occur, this product should be stopped:

- Hallucinations
- Restlessness
- Sleep disturbances

Severe Skin reactions
Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. This acute pustular eruption may occur within the first 2 days of treatment, with fever, and numerous, small, mostly non-follicular pustules arising on a widespread oedematous erythema and mainly localized on the skin folds, trunk, and upper extremities. Patients should be carefully monitored. If signs and symptoms such as pyrexia, erythema, or many small pustules are observed, administration of this medicine should be discontinued and appropriate measures taken if needed.

Ischaemic colitis
Some cases of ischaemic colitis have been reported with pseudoephedrine. Pseudoephedrine should be discontinued and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop.

Ischaemic optic neuropathy
Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs.

There have been rare cases of posterior reversible encephalopathy syndrome (PRES) / reversible cerebral vasoconstriction syndrome (RCVS) reported with sympathomimetic drugs, including pseudoephedrine. Symptoms reported include sudden onset of severe headache, nausea, vomiting, and visual disturbances. Most cases improved or resolved within a few days following appropriate treatment. Pseudoephedrine should be discontinued, and medical advice sought immediately if signs or symptoms of PRES/RCVS develop.

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.

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).

Patients with difficulty in urination and/or enlargement of the prostate should be advised to consult a physician before using this product.

Patients with the following conditions should not use Benylin Phlegm Cough plus Decongestant Syrup unless directed by a physician: acute or chronic asthma, a persistent or chronic cough or where cough is accompanied by excessive secretions. Patients should be advised to consult a physician if their cough lasts for more than 5 days or comes back, or is accompanied by a fever, rash or persistent headache.

The product should not be taken with a cough suppressant.

Patients with thyroid disease who are receiving thyroid hormones should not take pseudoephedrine unless directed by a physician.

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 mild to moderate renal impairment or severe hepatic impairment.

Use with caution in occlusive vascular disease.

This product may act as a cerebral stimulant giving rise to hyperpyrexia, tremor and epileptiform convulsions. Care should be taken when used in epileptic patients.

Pseudoephedrine may induce positive results in certain anti-doping tests.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-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 in to account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver or kidney disease or epilepsy.

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).

4.5 Interaction with other medicinal products and other forms of interactions

Sympathomimetic agents: Concomitant use of Benylin Phlegm Cough plus Decongestant Syrup with other sympathomimetic agents such as decongestants, tricyclic antidepressants, appetite suppressants and amphetamine-like psychostimulants may cause a rise in blood pressure. (See section 4.8)

Antihypertensives: 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, betanidine, reserpine, guanethidine, debrisoquine, methyldopa, adrenergic neurone blockers and beta-blockers.

MAOIs and/or RIMAs: Pseudoephedrine exerts its vasoconstricting properties by stimulating α-adrenergic receptors and displacing noradrenaline from neuronal storage sites. Since MAOIs impede the metabolism of sympathomimetic amines and increase the store of releasable norepinephrine in adrenergic nerve endings, MAOIs may potentiate the pressor effect of pseudoephedrine.
This medicine should not be used in patients treated with MAOIs or within 14 days of stopping treatment as there is an increased risk of hypertensive crisis.

Moclobemide: risk of hypertensive crisis.

Oxytocin: risk of hypertension.

Cardiac glycosides: increased risk of dysrhythmias.

Ergot alkaloids (ergotamine & methysergide): increased risk of ergotism.

Anticholinergic drugs: The effects of anti-cholinergics e.g., some psychotropic drugs (such as tricyclic antidepressants) and atropine, may be potentiated by this product giving rise to tachycardia, mouth dryness, gastrointestinal disturbances, e.g., colic, urinary retention and headache.

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

If urine is collected within 24 hours of a dose of Benylin Phlegm Cough plus Decongestant Syrup a metabolite of guaifenesin may cause a colour interference with laboratory determination of urinary 5-hydroxyindoleacetic acid (5-HIAA) and vanillylmandelic acid (VMA).

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 breastfeeding 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 pregnancy.

Breastfeeding
Pseudoephedrine is excreted in breast milk in small amounts, but the effect of this on breast-fed infants is not known. It has been estimated that approximately 0.4 to 0.7% of a single 60 mg dose of pseudoephedrine ingested by a nursing mother will be excreted in the breast milk over 24 hours. 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

Benylin Phlegm Cough plus Decongestant Syrup may have a minor influence on the ability to drive and use machines. Benylin Phlegm Cough plus Decongestant Syrup may cause dizziness. Patients should be cautioned about engaging in activities such as driving a car or operating machinery, until they have established their own response to the drug.

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, pseudoephedrine, or the combination of guaifenesin and pseudoephedrine 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	Hypersensitivity[1,2]- cross sensitivity may occur with other sympathomimetics
Psychiatric Disorders	Common	Insomnia[†,2] Nervousness[††,2]
	Rare	Hallucinations
	Not Known	Agitation[3] Anxiety[2] Delusion Euphoric mood[2] Hallucination, visual Irritability Restlessness Sleep disorder
Nervous System Disorders	Very common	Headache[2]
	Common	Dizziness[†,2]
	Not Known	Cerebrovascular accident Paraesthesia Posterior reversible encephalopathy syndrome (PRES) / Reversible cerebral vasoconstriction syndrome (RCVS Psychomotor hyperactivity Somnolence Tremor
Eye Disorders	Not known	Ischaemic opticneuropathy
Cardiac Disorders	Not Known	Arrhythmia[2] Myocardial infarction/Myocardial ischaemia Palpitations[2] Tachycardia[2]
Vascular Disorders	Not known	Hypertension

Gastrointestinal Disorders	Common	Dry mouth[†2] Nausea[†1,2]
	Not Known	Abdominal pain[1,3] Diarrhoea[1] Ischaemic colitis Vomiting[1]
Skin and Subcutaneous Tissue Disorders	Not known	Angioedema Pruritus[1,3] Rash[1] Severe skin reactions, including acute generalised exanthematous pustulosis (AGEP) Urticaria[1,3]
Renal and Urinary Disorders	Not Known	Dysuria[2] Urinary Retention[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
No differences between adult and paediatric safety profiles have been identified.

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, Website: www.hpra.ie.

4.9 Overdose

Signs and symptoms

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
When taken in excess, guaifenesin may cause renal calculi.

Pseudoephedrine
Overdose may result in:

Metabolism and nutrition disorders: hyperglycaemia, hypokalaemia

Psychiatric disorders: CNS stimulation, insomnia; irritability, restlessness, anxiety, agitation; confusion, delirium, hallucinations, psychoses

Nervous system disorders: seizures, tremor, intracranial haemorrhage including intracerebral haemorrhage, drowsiness in children

Eye disorders: mydriasis

Cardiac disorders: palpitations, tachycardia, reflex bradycardia, supraventricular and ventricular arrhythmias, dysrhythmias, myocardial infarction

Vascular disorders: hypertension, hypertensive crisis

Gastrointestinal disorders: nausea, vomiting, ischaemic bowel infarction

Musculoskeletal and connective tissue disorders: rhabdomyolysis

Renal and urinary disorders: acute renal failure, difficulty in micturition

Management

Necessary measures should be taken to maintain and support respiration and control convulsions. 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 ephedrine 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.

In a limited study, three mothers nursing healthy infants were given an antihistamine-decongestant preparation containing 60 mg of pseudoephedrine and 2.5 mg of triprolidine. Milk concentrations of pseudoephedrine were higher than plasma levels in all three patients, with peak milk concentrations occurring at 1.0–1.5 hours. The investigators calculated that 1000 ml of milk produced during 24 hours would contain approximately 0.5%–0.7% of the maternal dose. However, following a single-blind, crossover study of a single dose of pseudoephedrine 60 mg vs. placebo conducted in 8 lactating mothers, and assuming maternal intake of 60 mg pseudoephedrine hydrochloride four times daily, the estimated infant dose of pseudoephedrine based on AUC and an estimated milk production rate of 150 ml/kg/day was 4.3% (95% CI, 3.2, 5.4%; range 2.2 to 6.7%) of the weight-adjusted maternal dose.

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 (E 124)
Sunset Yellow (E110)
Wild Cherry flavour (contains ethanol, sodium and benzyl alcohol)
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 and other handling

No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Johnson & Johnson (Ireland) Limited
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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