Product Information for Benylin Chesty Coughs (Non-Drowsy), Benylin Chesty Coughs (Original), Benylin Dry Coughs 7.5mg-5ml Syrup, Benylin Dry Coughs Night Syrup, Benylin Mucus Cough, Benylin Mucus Cough plus Decongestant Syrup, Benylin Mucus Cough Max Menthol Flavour 100 mg-5 ml Oral Solution, Benylin Mucus Cough Night, Benylin Dry and Tickly Cough Syrup, Benylin Children's Chesty Coughs, Benylin Children's Dry Cough & Sore Throat Syrup or Benylin Dry & Tickly Cough Blackcurrant Syrup, Benylin Children's Night Coughs, Benylin Infant's Cough Syrup, Benylin Cold & Flu Max Strength Capsules, Benylin Four Flu Tablets, Benylin Day and Night Tablets, Benylin Mucus Cough Max Honey & Lemon Syrup, Benylin Herbal Chesty Coughs Sugar Free Syrup, Benylin Mucus Cough & Cold All in One Relief Tablets or Sudafed Mucus Relief Triple Action Cold & Flu Tablets, Benylin Herbal Cough & Cold Sugar Free Syrup

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/

Adverse events should also be reported to McNeil Products Limited on freephone 0808 238 9999.

Benylin Chesty Coughs (Non-Drowsy) (Guaifenesin, Levomenthol) Product Information

Presentation:
Red syrup containing 100 mg Guaifenesin and 1.1 mg Levomenthol per 5 ml.
Each 5 ml also contains: Ethanol 197 mg, Glucose 3.5 g, Sucrose 1 g, Sodium 16.43 mg, Sodium benzoate (E 211) 10 mg, Ponceau 4R (E 124) 0.25 mg.
Uses:
Symptomatic relief of cough.
Dosage:
Adults and children aged 12 years and over: 10 ml syrup every 4 - 6 hours up to 4 times a day
Contraindications:
Known hypersensitivity to ingredients. Use in children under 12 years.
Precautions:
Do not use in persistent or chronic cough, e.g., asthma, or cough accompanied by excessive secretions; caution in severe renal or hepatic impairment. Contains 3.5 g of glucose and 1 g of sucrose per 5 ml. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. This medicine contains 197 mg of alcohol (ethanol) per 5 ml dose. The amount in 5 ml of this medicine is equivalent to less than 5 ml beer or 2 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects. This medicinal product contains 16.43 mg sodium per 5 ml dose, equivalent to 0.82% of the

WHO recommended maximum daily intake of 2 g sodium for an adult. This medicine contains 10 mg sodium benzoate (E 211) in each 5 ml. This product contains Ponceau 4R (E124) red colouring which may cause allergic reactions.

Pregnancy and Lactation:

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

Side effects:

Hypersensitivity reactions (hypersensitivity, pruritus and urticaria), rash. Abdominal pain upper, diarrhoea, nausea, vomiting

RRP (ex-VAT): 125ml £4.00; 150ml £6.58; 300ml £8.74.

Legal category: GSL.

PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

PL Number: 15513/0056.

Date of preparation: 16 FEB 2022

Benylin Chesty Coughs (Original) (Diphenhydramine hydrochloride, Levomenthol) Product Information

Presentation:

Red syrup containing 14mg Diphenhydramine HCl and 2mg Levomenthol per 5ml.

Sucrose 1 g, Liquid glucose 3.5 g, Ethanol 197 mg, Ponceau 4R (E 124) 0.25 mg, Sodium 16.62 mg, Benzyl alcohol 0.22 mg, Sodium benzoate (E 211) 10 mg.

Uses:

Relief of cough and associated congestive symptoms.

Dosage:

Adults and Children aged 12 years and over: One 10 ml dose of syrup 4 times a day. Maximum daily dose: 40 ml syrup.

Contraindications:

Known hypersensitivity to Diphenhydramine, L-menthol or to any of the excipients listed within the Summary of Product Characterises (SmPC). BENYLIN CHESTY COUGHS (ORIGINAL) should not be administered to patients currently receiving monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping treatment. Not to be used in children under the age of 12 years.

Precautions:

May cause drowsiness, if affected, do not drive or operate machinery. This product should not be used to sedate a child. Patients with the following conditions should consult a physician before using this medicine: A chronic or persistent cough such as occurs with chronic bronchitis or emphysema, acute or chronic asthma, or where cough is accompanied by excessive secretions, susceptibility to angle-closure glaucoma, prostatic hypertrophy and/or, urinary retention. Contains 3.5 g of glucose and 1 g of sucrose per 5 ml. This should be taken into account in patients with diabetes mellitus.

Patients with hepatic disease or moderate to severe renal dysfunction should exercise caution when using this product. Alcoholic beverages should be avoided while taking this medicine. May potentiate effects of alcohol, opioid analgesics, antipsychotics, antihistamines and other CNS depressants. May enhance the effects of anticholinergics. Do not use with any other product containing diphenhydramine. This product contains Ponceau 4R (E124) red colouring which may cause allergic reactions. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. This medicine contains 0.22 mg benzyl alcohol in each 5ml. Benzyl alcohol may cause allergic reactions. This medicine contains 10 mg sodium benzoate (E 211) in each 5 ml. This medicine contains 197 mg of alcohol (ethanol) in each 5 ml. The amount in 5 ml of this medicine is equivalent to less than 5 ml beer or 2ml wine. The small amount of alcohol in this medicine will not have any noticeable effects. Please consult the SmPC for further precautions.

Pregnancy and lactation:

This product should not be used during pregnancy or breast-feeding unless the potential benefit of treatment to the mother outweighs the possible risks to the developing foetus or breastfeeding infant. 'Diphenhydramine has been in widespread use for many years without any apparent ill consequence. Diphenhydramine is known to cross the placenta and, therefore, should only be used during pregnancy if considered essential by a doctor. Diphenhydramine is excreted into human breast milk, but levels have not been reported. Although the levels are not thought to be sufficiently high enough after therapeutic doses to affect the infant, the use of diphenhydramine during breast-feeding is not recommended. There are no adequate and well-controlled studies in pregnant women for menthol. Menthol is excreted in breast milk; when 100 mg of menthol was ingested, there was up to 5.87 ug/L of menthol in breast milk

Side effects:

Very Common: Somnolence **Common**: Dizziness, Headache, Paradoxical stimulation, Psychomotor impairment, Thickened respiratory tract Secretions, dry mouth, Nausea Vomiting, Asthenia, Vision blurred **Uncommon**: Irritability Hallucination Nervousness, Agitation, Paraesthesia, Sedation, Tinnitus, Tachycardia, Chest discomfort, Nasal Dryness, Pruritus, Urticaria. **Rare** Blood disorders, Confusional state, Convulsion, Depression, Extrapyramidal effects, Tremor, Arrhythmia
Palpitations, Hypotension, Liver dysfunction

RRP (ex-VAT): 150ml £6.66; 300ml £9.91

Legal category: P.

PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK

PL Number: 15513/0048.

Date of preparation: 22 JUN 2023

Benylin Dry Coughs 7.5mg/5ml Syrup (dextromethorphan hydrobromide) Product Information

Presentation:
Brown syrup containing 7.5mg dextromethorphan hydrobromide per 5ml.
Each 5ml also contains: Sucrose 1.6g, Liquid glucose 2.38g, Sorbitol 325mg, Ethanol 236 mg, Sodium benzoate 25 mg, Propylene glycol 2.72 mg.
Uses:
This product is indicated as an antitussive, for the relief of an unproductive cough.
Dosage:
Adults: 10ml four times daily.
Contraindications:
Use in children under 12 years. Known hypersensitivity to ingredients.
Dextromethorphan should not be used in patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOI treatment. There is a risk of serotonin syndrome with the concomitant use of dextromethorphan and MAOIs and the concomitant use of these medications may cause a rise in blood pressure and/or hypertensive crisis.
Precautions:
Patients with the following conditions should not use this product, unless directed by a physician: acute or chronic asthma, a persistent or chronic cough such as occurs with chronic bronchitis or emphysema, or where cough is accompanied by excessive secretions. Caution in hepatic impairment.
For all patients, prolonged use of this product may lead to drug dependence (addiction), even at therapeutic doses. The risks are increased in individuals with current or past history of substance misuse disorder (including alcohol misuse) or mental health disorder (e.g. major depression). Drug withdrawal syndrome is characterised by some or all of the following: restlessness, lacrimation, rhinorrhoea, yawning, perspiration, chills, myalgia, mydriasis and palpitations. Other symptoms may also develop including irritability, agitation, anxiety, hyperkinesia, tremor, weakness, insomnia, anorexia, abdominal cramps, nausea, vomiting, diarrhoea, increased blood pressure, increased respiratory rate or heart rate. Serotonergic effects, including the development of a potentially life-threatening serotonin syndrome, have been reported for dextromethorphan with concomitant administration of serotonergic agents, such as selective serotonin re-uptake inhibitors (SSRIs), drugs which impair metabolism of serotonin (including MAOIs) and CYP2D6 inhibitors. If serotonin syndrome is suspected, treatment with this medicine should be discontinued. Do not take with other cough and cold medicines. Use of dextromethorphan with alcohol or other CNS depressants may increase the effects on the CNS and cause toxicity in relatively smaller doses. While taking this product, patients should be advised to avoid alcoholic drinks and consult a healthcare professional prior to taking with central nervous system depressants.
Caution in patients who are slow metabolisers of CYP2D6 or use CYP2D6 inhibitors.
Caution in atopic children due to histamine release.
Caution due to the following excipients:

- This product contains 2.38 g glucose and 1.6 g sucrose per 5ml. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary

problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

- This medicine contains 325 mg sorbitol in each 5 ml dose. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.
- This medicine contains 25 mg benzoate salt in each 5 ml dose. This medicine contains 2.72 mg propylene glycol in each 5 ml dose.
- This medicine contains 236 mg of alcohol (ethanol) in each 5 ml dose. The small amount of alcohol in this medicine will not have any noticeable effects.

See SPC for further precautions
Pregnancy and lactation:
There are no adequate and well-controlled studies in pregnant women. It is not known whether dextromethorphan or its metabolites are excreted in breast milk. Dextromethorphan should not be used during pregnancy or lactation unless the potential benefit of treatment to the mother outweighs the possible risk to the developing foetus or nursing infant.
Side effects:
Angioedema, pruritus, rash, urticaria, insomnia, agitation, confusional state, seizure, dizziness, psychomotor hyperactivity, somnolence, respiratory depression, abdominal pain, diarrhoea, gastrointestinal disorder, nausea, vomiting**,** drug dependence and drug withdrawal syndrome.
RRP (ex-VAT): 150 ml £6.99
Legal category: P
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG
PL Number: 15513/0051
Date of preparation: 04 MAY 2022

Benylin Dry Coughs Night Syrup (Diphenhydramine hydrochloride, Dextromethorphan hydrobromide, Levomenthol) Product Information

Presentation:
Red syrup containing 14mg Diphenhydramine hydrochloride, 6.5mg Dextromethorphan hydrobromide and 2mg Levomenthol per 5ml. Each 5ml also contains:
Ethanol 196 mg, Glucose 3.5 g, Sucrose 1 g, Ponceau 4R (E124) 0.25 mg, Sodium 16.7 mg, Benzyl alcohol 0.48 mg, Propylene glycol 2.61 mg, Sodium benzoate (E211) 10 mg.
Uses:
For night time relief of persistent, dry, irritating cough and aiding restful sleep.
Dosage:
Adults and children over 12 years: two 5 ml spoonfuls at bedtime followed by two 5 ml spoonfuls every 6 hours. Do not take more than 4 doses in 24 hours.
Contraindications:

Use in children under 12 years. Contraindicated in individuals with known hypersensitivity to diphenhydramine, dextromethorphan, levomenthol or to any of the excipients listed. Dextromethorphan should not be used in patients taking monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOI treatment. There is a risk of serotonin syndrome with the concomitant use of dextromethorphan and MAOIs and the concomitant use of these medications may cause a rise in blood pressure and/or hypertensive crisis. Patients taking serotonin reuptake inhibitors. Patients in or at risk of developing respiratory failure.

Precautions:

May cause drowsiness. This should not be used to sedate a child.

Patients with the following conditions should not use this product, unless directed by a physician: acute or chronic asthma, a persistent or chronic cough such as occurs with chronic bronchitis or emphysema, or where cough is accompanied by excessive secretions.

Diphenhydramine should be used with caution by individuals with susceptibility to angle-closure or with prostatic hypertrophy, urinary retention. Use with caution in moderate to severe renal impairment or hepatic dysfunction Drug dependence, tolerance and potential for abuse for all patients, prolonged use of this product may lead to drug dependence (addiction), even at therapeutic doses. The risks are increased in individuals with current or past history of substance misuse disorder (including alcohol misuse) or mental health disorder (e.g., major depression). Drug withdrawal syndrome is characterised by some or all of the following: restlessness, lacrimation, rhinorrhoea, yawning, perspiration, chills, myalgia, mydriasis and palpitations. Other symptoms may also develop including irritability, anxiety, hyperkinesia, tremor, weakness, insomnia, anorexia, abdominal cramps, nausea, vomiting, diarrhoea, increased blood pressure, increased respiratory rate or heart rate. Serotonergic effects, including the development of a potentially life-threatening serotonin syndrome, have been reported for dextromethorphan with concomitant administration of serotonergic agents, such as selective serotonin re-uptake inhibitors (SSRIs), drugs which impair metabolism of serotonin (including monoamine oxidase inhibitors (MAOIs)) and CYP2D6 inhibitors. If serotonin syndrome is suspected, treatment with this medicine should be discontinued.

Caution in patients who are slow metabolizers of CYP2D6 or use CYP2D6 inhibitors.

Use of dextromethorphan with alcohol or other CNS depressants may increase the effects on the CNS and cause toxicity in relatively smaller doses. Diphenhydramine may enhance the sedative effects of central nervous system depressants including alcohol, opioid analgesics, antipsychotics, sedatives, and tranquilizers.

Caution in atopic children due to histamine release. Do not use with any other product containing diphenhydramine including topical formulations used on large areas of skin.

This product should not be taken with any other cough and cold medicines.

Caution due to the following excipients:

- This product contains Ponceau 4R (E124) red colouring which may cause allergic reactions.
- This product contains 16.7 mg sodium per 5 ml, equivalent to 0.835% of the WHO recommended maximum daily intake of 2 g sodium for an adult.
- This product contains 3.5 g glucose and 1 g sucrose per 5ml. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or

sucrase-isomaltase insufficiency should not take this medicine. This should be taken into account in patients with diabetes mellitus.
- This medicine contains 10 mg sodium benzoate (E211) in each 5 ml.
- This medicine contains 2.61 mg propylene glycol in each 5 ml.
- This medicine contains 0.48 mg benzyl alcohol in each 5 ml. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. Ask your doctor or pharmacist for advice if you have a liver or kidney disease.
- This medicine contains 196 mg of alcohol (ethanol) in each 5 ml. The amount in 5 ml of this medicine is equivalent to less than 5 ml beer or 2 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

See SPC for further precautions.
Pregnancy and lactation:
This medicine should not be used during pregnancy or lactation unless the potential benefit of treatment to the mother outweighs the possible risk to the developing foetus or breastfeeding infant.
Side effects:
Very common: Somnolence
Common: Dizziness, Headache, Paradoxical stimulation, Psychomotor impairment, Blurred vision, Increased viscosity of bronchial secretion, Dry Mouth, Gastrointestinal disorder, Urinary retention, Asthenia
Uncommon: Confusional state, Insomnia, Irritability, Nervousness, Tinnitus, Rash
Rare: Blood disorder, Hypersensitivity, Depression, Sleep disorder, Extrapyramidal disorder, Seizure, Tremor, Arrhythmia, Palpitations, Hypotension, Liver Disorder
Very rare:
Not known: Agitation, Drug dependence, Hallucination, Paraesthesia, Tachycardia, Chest discomfort, Nasal dryness, Respiratory depression, Abdominal pain, Diarrhoea, Nausea, Vomiting, Angioedema, Pruritus, Urticaria, Dysuria, Drug withdrawal syndrome
RRP (ex-VAT): 150 ml £6.66
Legal category: P.
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK
PL Number: 15513/0053.
Date of preparation: 12 June 2023

Benylin Mucus Cough (Guaifenesin, Levomenthol) Product Information

Presentation:
Red syrup containing 100 mg Guaifenesin and 1.1 mg Levomenthol per 5 ml.
Each 5 ml also contains: Ethanol 197 mg, Glucose 3.5 g, Sucrose 1 g, Sodium 16.43 mg, Sodium benzoate (E 211) 10 mg, Ponceau 4R (E 124) 0.25 mg.

Uses:
Symptomatic relief of cough.
Dosage:
Adults and children aged 12 years and over: 10 ml syrup every 4 - 6 hours up to 4 times a day.
Contraindications:
Known hypersensitivity to ingredients. Use in children under 12 years.
Precautions:
Do not use in persistent or chronic cough, e.g. asthma, or cough accompanied by excessive secretions; caution in severe renal or hepatic impairment. Contains 3.5 g of glucose and 1 g of sucrose per 5 ml. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. This medicine contains 197 mg of alcohol (ethanol) per 5 ml dose. The amount in 5 ml of this medicine is equivalent to less than 5 ml beer or 2 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects. This medicinal product contains 16.43 mg sodium per 5 ml dose, equivalent to 0.82% of the WHO recommended maximum daily intake of 2 g sodium for an adult. This medicine contains 10 mg sodium benzoate (E 211) in each 5 ml. This product contains Ponceau 4R (E124) red colouring which may cause allergic reactions.
Pregnancy and Lactation:
This product is not recommended during pregnancy and in women of childbearing potential not using contraception. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from this product, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.
Side effects:
Hypersensitivity reactions (hypersensitivity, pruritus and urticaria), rash. Abdominal pain upper, diarrhoea, nausea, vomiting
RRP (ex-VAT): 125ml £4.00; 150ml £5.83; 300ml £7.97.
Legal category: GSL.
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.
PL Number: 15513/0056.
Date of preparation: 16 FEB 2022.

Benylin Mucus Cough plus Decongestant Syrup (Guaifenesin, Pseudoephedrine) Product Information

Presentation:
Orange-red syrup containing 100mg guaifenesin and 30mg pseudoephedrine hydrochloride per 5ml.
Each 5ml also contains sucrose 3g, methyl hydroxybenzoate (E 218) 5mg, propyl hydroxybenzoate (E 216) 0.5mg, ethanol 96 %v/v 190mg, Ponceau 4R (E 124) 0.25mg, Sunset Yellow (E 110) 0.25mg, benzyl alcohol 0.02mg
Uses:

Symptomatic relief of upper respiratory tract disorders with productive cough.

Dosage:

Adults and children over 12 years: 10 ml every 4 to 6 hours up to four times daily.

Contraindications:

This product is contraindicated in children under the age of 12 years. It is also contraindicated in individuals with known hypersensitivity to guaifenesin, pseudoephedrine, or to any of the product's excipients; cardiovascular disease including hypertension, diabetes mellitus, phaeochromocytoma, hyperthyroidism, closed angle glaucoma, severe acute or chronic kidney disease/renal failure. This product should not be used by individuals who are concomitantly taking beta blockers, or other sympathomimetic decongestants, and in individuals who are taking, or who have taken monoamine oxidase inhibitors (MAOIs) within the preceding 14 days. The concomitant use of MAOIs and pseudoephedrine-containing products may result in a rise in blood pressure and/or hypertensive crisis.

Precautions:

Patients with thyroid disease who are receiving thyroid hormones should not take pseudoephedrine unless directed by a physician. Patients with the following conditions should be advised to consult a physician before using this product: difficulty in urination and/or enlargement of the prostate; a respiratory condition such as emphysema, chronic bronchitis or acute or chronic bronchial asthma. This product should be not used for persistent or chronic cough, such as occurs with asthma, or emphysema where cough is accompanied by excessive secretions, unless directed by a physician.

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.

Caution should be exercised when using this product in the presence of severe hepatic impairment or moderate to severe renal impairment (particularly if accompanied by cardiovascular disease), or occlusive vascular disease. This product should be stopped if hallucinations, restlessness, or sleep disturbances occur.

Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. 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.

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.

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported with the use of pseudoephedrine-containing products. The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure. Pseudoephedrine should be discontinued, and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances.

This product contains the following excipients:

- 3g of sucrose per 5ml, which should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance,

glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.
- Less than 1mmol sodium (23mg) per 5ml, that is to say essentially 'sodium free.'
- 0.02 mg benzyl alcohol in each 5 ml. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding.
- Ponceau 4R (E 124) red colouring and sunset yellow (E 110) which may cause allergic reactions.
- Methyl hydroxybenzoate (E 218) and propyl hydroxybenzoate (E 216) which may cause possibly delayed allergic reactions.
- 190 mg of alcohol (ethanol) in each 5 ml. The amount in 5 ml of this medicine is equivalent to less than 5 ml beer or 2 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Please refer to Summary of Product Characteristics for detailed information.

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.

Side effects:

Very common: headache

Common: insomnia, nervousness, dizziness, dry mouth, nausea

Not Known: hypersensitivity (cross-sensitivity with other sympathomimetics), anxiety, euphoric mood, excitability, hallucinations, irritability, paranoid delusions, restlessness, sleep disorder, cerebrovascular accident, paraesthesia, posterior reversible encephalopathy syndrome (PRES)/reversible cerebral vasoconstriction syndrome (RCVS), psychomotor hyperactivity, somnolence, tremor, ischaemic optic neuropathy, dysrhythmias, myocardial infarction/myocardial ischaemia, palpitations, tachycardia, hypertension, abdominal pain, diarrhoea, ischaemic colitis, vomiting, angioedema, pruritus, rash, severe skin reactions including acute generalised exanthematous pustulosis (AGEP), urticaria, dysuria, urinary retention (in men in whom prostatic enlargement could have been an important predisposing factor)

Please refer to Summary of Product Characteristics for detailed information.

RRP (ex-VAT): 100ml: £4.99

Legal category: P

PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, BuckinghamshireHP12 4EG, UK

PL Number: 15513/0022

Date of preparation: 16 May 2024

Benylin Mucus Cough Max Menthol Flavour 100 mg/5 ml Oral Solution (Guaifenesin) Product Information

Presentation:

Red syrup containing 100 mg Guaifenesin per 5 ml.

Uses:

To help loosen phlegm and thin bronchial secretions associated with productive cough.

Dosage:

Adults and children over 12 years: 10 ml four times daily, max 40ml daily. Not recommended in children under 12 years.

Contraindications:

Hypersensitivity to the active substance or to any of the excipients

Precautions:

Do not use in persistent or chronic cough, e.g. asthma, or cough accompanied by excessive secretions; caution in severe renal or hepatic impairment; rare hereditary problems of fructose intolerance, glucose galactose malabsorption. Concomitant use of cough suppressants not recommended. This product contains ethanol. This product contains Ponceau 4R (E124) which may cause allergic reactions. This product contains sodium and this should be taken into consideration by those on a controlled sodium diet. This medicinal product contains 10 mg of benzoate salt in each 10 ml dose. This medicinal product may contain very trace amounts of glucose. A dose of 10 ml of this medicine administered to a child 12 years of age and weighing 35 kg would result in exposure to 10.9 mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 1.81 mg/100 ml. A dose of 10 ml of this medicine administered to an adult weighing 70 kg would result in an exposure of 5.4 mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 0.9 mg/100 ml. (see Appendix 1 of report EMA/CHMP/43486/2018). For comparison, for an adult drinking a glass of wine or 500 ml of beer, the BAC is likely to be about 50 mg/100 ml. Co-administration with medicines containing e.g. propylene glycol or ethanol may lead to accumulation of ethanol and induce adverse effects, in particular in young children with low or immature metabolic capacity. This medicinal product contains less than 1 mmol sodium (23 mg) per 10 ml dose, that is to say essentially ‘sodium-free’. Medical monitoring is required in patients with impaired renal or hepatic functions because various adverse events attributed to propylene glycol have been reported such as renal dysfunction (acute tubular necrosis), acute renal failure and liver dysfunction. This medicinal product contains macrogol glycerol hydroxystearate 40. It may cause stomach upset and diarrhoea.

Pregnancy and Lactation:

Benylin Mucus Cough Max Menthol Flavour 100 mg/5 ml

Oral Solution is not recommended during pregnancy and in women of childbearing potential not using contraception. Breast-feeding Guaifenesin is excreted in breast milk in small amounts. There is insufficient information on the effects of guaifenesin in newborns/infants. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Benylin Mucus Cough Max Menthol flavour 100 mg/5 ml Oral Solution therapy, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. This medicinal product contains 2003.5 mg propylene glycol in each 10 ml dose. While propylene glycol has not been shown to cause reproductive or developmental toxicity in animals or humans, it may reach the foetus and was found in milk. As a consequence, administration of propylene glycol to pregnant or lactating patients should be considered on a case by case basis.

Side effects:

Frequency not known: Abdominal pain upper, diarrhoea, nausea, vomiting, hypersensitivity reactions including pruritus, urticaria and rash.
RRP (ex-VAT): 150ml £6.58
Legal category: GSL.
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK
PL Number: 15513/0165.
Date of preparation: 23 Mar 2023

Benylin Mucus Cough Night (Guaifenesin, Levomenthol, Diphenhydramine) Product Information

Presentation:
A clear red syrup with no insoluble matter containing 100 mg Guaifenesin, 1.1 mg Levomenthol and 14mg Diphenhydramine per 5 ml. Also contains 0.259ml Ethanol, 3492mg Glucose and 999mg Sucrose per 5ml.
Uses:
For the relief of cough (dry and/or chesty), associated congestive symptoms and aiding restful sleep.
Dosage:
Adults, the elderly, and children over 12 years: Two 5 ml spoonfuls four times a day. Or to aid sleep patients may start with two 5 ml spoonfuls at bedtime followed by two 5 ml spoonfuls every 6 hours. Do not take more than 4 doses (1 dose = two 5 ml spoonfuls) in 24 hours.
Contraindications:
Children under 12 years. Known hypersensitivity to diphenhydramine, guaifenesin, levomenthol, or any of the product's excipients. Not for use in patients currently receiving monoamine oxidase inhibitors (MAOIs) within 14 days of stopping treatment.
Precautions:
May cause drowsiness This product should not be used to sedate a child. Subjects with moderate to severe renal dysfunction or hepatic disease should exercise caution when using this product.
Do not use with any other product containing diphenhydramine including topical formulations used on large areas of skin. Diphenhydramine may enhance the sedative effects of central nervous system depressants, including alcohol, opioid analgesics, antipsychotics, sedatives, and tranquilizers. Patients should be advised while taking this product to avoid alcoholic beverages and consult a healthcare professional prior to taking with central nervous system depressants. Excitability may occur. Patients with the following conditions should be advised to consult a physician before using this product: Acute or chronic bronchial asthma, persistent or chronic cough such as occurs with smoking, asthma chronic bronchitis or emphysema or where cough is accompanied by excessive secretions, susceptibility to narrow angle-closure glaucoma, prostatic enlargement (hyperplasia/hypertrophy) with and/or urinary retention. Do not take with a cough suppressant.
Caution regarding the following excipients:

- This product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
- This product contains 6.984 g glucose per 10 ml dose. This should be taken into account in patients with diabetes mellitus. Patients with rare glucose galactose malabsorption should not take this medicine.
- This product contains Ponceau 4R (E124) red colouring which may cause allergic reactions.
- This product contains 5 vol % ethanol (alcohol), i.e. up to 200 mg per 5ml dose, which is 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 disease or epilepsy.

See SPC for further precautions.

Pregnancy and Lactation:

Insufficient information is available on the effects of administration of this product during human pregnancy. 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.

Side effects:

Very common: Somnolence (usually diminishes within a few days), Sedation.
Common: Dizziness, Headache, Paradoxical stimulation, Psychomotor impairment, Blurred vision, Dry throat, Increased viscosity of bronchial secretion, Dry mouth, Gastrointestinal disorder, Urinary retention, Asthenia.
Uncommon: Agitation, Insomnia, Irritability, Nervousness, Tinnitus, Rashes.
Rare: Blood disorder, Hypersensitivity, Confusional state, Depression, Sleep disorder, Convulsion, Extrapyramidal disorder, Tremor, Arryhthmia, Palpitations, Hypotension, Liver disorder.
Not known: Angioedema, Hallucination, Coordination abnormal, Paraesthesia, Tachycardia, Nasal dryness, Abdominal discomfort, Abdominal pain upper, Constipation, Diarrhoea, Dyspepsia, Nausea, Vomiting, Erythema, Pruritus, Urticaria, Dysuria, Chest discomfort.

RRP (ex-VAT): 150ml £7.57
Legal category: P
PL Holder: McNeil Products Limited 50 – 100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom
PL Number: 15513/0050.
Date of preparation: 26 September 2023

Benylin Dry and Tickly Cough Syrup (Glycerol, Sucrose) Product Information

Presentation:

Liquid containing 0.75ml Glycerol and 1.707g Sucrose per 5ml.

Uses:
For the relief of irritating, tickling dry coughs and sore throats.
Dosage:
Adults and children over 5 years: 10ml 3 to 4 times a day; children 1 – 5 years: 5 ml 3 to 4 times a day; children under 1 year: not to be given.
Contraindications:
Known hypersensitivity or intolerance to ingredients.
Precautions:
Diabetics should take note of the carbohydrate content of this product. This medicine contains sucrose and glucose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. This medicine contains 5 mg of alcohol (ethanol) in each 5 ml dose. The amount in 5 ml of this medicine is equivalent to less than 1 ml beer or wine. The small amount of alcohol in this medicine will not have any noticeable effects. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.
Consult SPC for further precautions
Pregnancy and Lactation:
The safety of this product during pregnancy and lactation has not been established. Consult doctor before use.
RRP (ex-VAT): 150ml £5.95, 300ml £8.32.
Legal category: GSL.
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG
PL Number: 15513/0142.
Date of preparation: 10 MAR 2021

Benylin Children's Chesty Coughs (Guaifenesin) Product Information:

Presentation:
Syrup containing 50mg Guaifenesin per 5ml.
Indications:
Symptomatic relief of acute productive (chesty) coughs.
Dosage and Administration:
Children 6 – 12 years: 10 ml 4 times daily, max daily dose 40ml.
Contraindications:
Use in children under 6 years. Hypersensitivity.
Precautions:
Not to be used for more than 5 days without the advice of a doctor. Parents and carers should seek medical attention if the child's condition deteriorates during treatment; do not use with cough suppressants; caution in chronic cough or asthma; caution in severe renal or hepatic impairment. See SPC for further details.

Excipient warning: This medicine contains 5.05g sorbitol in each 10 ml dose. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product. Sorbitol may cause gastrointestinal discomfort and mild laxative effect. This medicine contains 25.2 mg benzoate salt in each 10 ml dose. This medicine contains 0.1 mg benzyl alcohol in each 10 ml dose. Benzyl alcohol may cause allergic reactions. This medicine must be used with caution in patients with renal or hepatic impairment, or in patients who are pregnant or breast-feeding, because of the risk of accumulation and toxicity (metabolic acidosis).

Pregnancy and lactation:

This medicine must be used with caution in patients who are pregnant or breast-feeding.

BENYLIN Children's Chesty Coughs is not recommended during pregnancy and in women of childbearing potential not using contraception.

Side effects:

Frequency not known: Hypersensitivity reactions (hypersensitivity, pruritus, urticaria), rash, abdominal pain upper, diarrhoea, nausea, vomiting.

RRP (ex-VAT): 125 ml £4.66

Legal Category: P

PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK

PL Number: 15513/0052

Date of Preparation: 26 October 2022

Benylin Children’s Dry Cough & Sore Throat Syrup or Benylin Dry & Tickly Cough Blackcurrant Syrup (Glycerol, Sucrose) Product Information

Presentation:

A dark red, blackcurrant flavored syrup containing glycerol 0.75ml, sucrose 1.7g per 5ml.

Uses: For the relief of irritating, tickling dry coughs and sore throats.

Dosage:

Adults, elderly, and children over 5 years: 10ml. Children 1 – 5 years: 5ml. The dose may be repeated three or four times a day.

Contraindications: In children under 1 year. Hypersensitivity to the active substances or to any of the excipients listed in SPC section 6.1.

Warnings and Precautions:

Diabetics should take note of the carbohydrate content of this product. Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. This medicine contains

3.53mg propylene glycol (E1520) in each 5ml dose, which is equivalent to 0.71mg/ml. This medicine contains 10mg sodium benzoate (E211) in each 5ml which is equivalent to 2mg/ml. This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially 'sodium-free'. This medicine contains 0.000053mg benzyl alcohol in each 5ml which is equivalent to 0.000011mg/ml. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis"). Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist. This is due to an increased risk due to accumulation in young children.

Fertility, pregnancy and lactation:
The safety of this medicine during pregnancy and lactation has not been established but is not considered to constitute a hazard during these periods.

Side-effects: hypersensitivity reactions, including anaphylaxis.
RRP (ex-VAT): 125ml, £4.07
Legal category: GSL.
PL holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG
PL number: 15513/0392.
Date of preparation: 19 JUL 2022

Benylin Children's Night Coughs (Diphenhydramine hydrochloride, Levomenthol) Product Information

Presentation: Syrup containing 7mg Diphenhydramine HCl and 0.55mg Levomenthol per 5ml. Each 5ml also contains the following excipients: Sorbitol (E 420) 2.53g, Ethanol 197mg, Sodium 16.47mg, Sodium benzoate (E 211) 25mg.
Uses: Relief of cough and associated congestive symptoms, runny nose, sneezing, and treatment of hayfever and other allergic conditions affecting the upper respiratory tract.
Dosage: Children 6 - 12 years: 10ml every 6 hours.
Contraindications: Use in children under 6 years; hypersensitivity to Diphenhydramine or Levomenthol (or menthol) or to any of the excipients. BENYLIN CHILDREN'S NIGHT COUGHS should not be administered to patients currently receiving monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping treatment.
Precautions:
Not to be used for more than five days without the advice of a doctor; parents or carers should seek medical attention if the child's condition deteriorates during treatment; Patients with the following conditions should be advised to consult a physician before using:

- A chronic or persistent cough such as occurs with emphysema
- or chronic bronchitis, acute or chronic asthma, or where cough is accompanied by excessive secretions

- Susceptibility to angle-closure glaucoma
- Prostatic hypertrophy, and/or urinary retention.

Diphenhydramine may enhance the sedative effects of central nervous system depressants including alcohol, sedatives, opioid analgesics, antipsychotics and tranquilizers. Alcoholic beverages should be avoided while taking this medicine.
Do not use with any other product containing diphenhydramine, including topical formulations used on large areas of skin.
Patients with hepatic disease or moderate to severe renal dysfunction should exercise caution when using this product.
The product may cause drowsiness. This product should not be used to sedate a child.
A dose of 10 ml of this medicine administered to a child 6 years of age and weighing 21 kg would result in exposure to 18.8 mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 3.13 mg/100 ml. For comparison, for an adult drinking a glass of wine or 500 ml of beer, the BAC is likely to be about 50 mg/100 ml.
Co-administration with medicines containing e.g., propylene glycol or ethanol may lead to accumulation of ethanol and induce adverse effects, in particular in young children with low or immature metabolic capacity.
This medicine contains 16.47 mg sodium (main component of cooking/table salt) in each 5 ml. This is equivalent to 0.82% of the recommended maximum daily dietary intake of sodium for an adult.
This product contains 2.53 g sorbitol in each 5ml. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly. Patients with hereditary problems of fructose intolerance (HFI) should not take this medicinal product. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
This medicine contains 25 mg sodium benzoate in each 5 ml.

Interactions:

Diphenhydramine

CNS depressants: may enhance the sedative effects of CNS depressants including barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives, antipsychotics, and alcohol.
Antimuscarinic drugs**:** may have an additive muscarinic action with other drugs; such as atropine and some antidepressants.
MAOIs: Not to be used in patients taking MAOIs or within 14 days of stopping treatment as there is a risk of serotonin syndrome.
Pregnancy and lactation: This product should not be used during pregnancy or breast-feeding unless the potential benefit of treatment to the mother outweighs the possible risks to the developing foetus or breastfeeding infant.
Diphenhydramine
Pregnancy - Diphenhydramine has been in widespread use for many years without any apparent ill consequence. Diphenhydramine is known to cross the placenta and, therefore, should only be used during pregnancy if considered essential by a doctor.
Breast-feeding- Diphenhydramine is excreted into human breast milk, but levels have not been reported. Although the levels are not thought to be sufficiently high enough

after therapeutic doses to affect the infant, the use of diphenhydramine during breast-feeding is not recommended.

Menthol

There are no adequate and well-controlled studies in pregnant women for menthol. Menthol is excreted in breast milk; when 100 mg of menthol was ingested, there was up to 5.87 ug/L of menthol in breast milk.

Side effects:

Very Common: Somnolence

Common: Asthenia, Nausea

Vomiting, Dizziness, paradoxical stimulation, headache, psychomotor impairment, urinary retention, dry mouth, blurred vision, thickened respiratory tract secretions.

Uncommon: Irritability, Hallucination, Nervousness, Agitation, Paraesthesia, Sedation, Tinnitus, Tachycardia, Chest Discomfort, Nasal Dryness, Pruritus, Rash, Urticaria

Rare: hypotension, extrapyramidal effects, Confusional state, depression, insomnia, tremor, convulsions, palpitation, arrhythmia, hypersensitivity reactions, blood disorders and liver dysfunction.

RRP (ex-VAT): 125 ml £4.66
Legal category: P.
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK
PL Number: 15513/0044.
Date of preparation: 22 JUN 2023

Benylin Infant's Cough Syrup - Product Information

Presentation:

Syrup containing 0.75ml Glycerol per 5ml (15%v/v).

Uses:

Relief of dry tickly coughs.

Dosage:

Children aged 1 – 5 years: two 5ml spoonfuls three to four times a day.; Children 3 months – 1 year: one 5ml spoonful three to four times a day; Children under 3 months: not recommended.

Contraindications:

Hypersensitivity to ingredients; fructose intolerance.

Precautions:

Diabetics should take note that glycerol may affect blood sugar levels.
If symptoms persist for more than 3 days or get worse, patients should stop use and consult a doctor. This medicine contains less than 1 mmol sodium (23 mg) per 5ml, that is to say essentially 'sodium-free'. This medicine contains 10 mg sodium benzoate (E211) in each 5ml which is equivalent to 2mg/ml. This medicine contains 18.24 mg

propylene glycol (E1520) in each 5ml which is equivalent to 3.65mg/ml.

Pregnancy and Lactation:

Not applicable.

Side Effects:

Possible mild laxative effect.

RRP (ex-VAT): 125ml £4.07

Legal category: GSL.

PL Holder: McNeil Products Ltd**,** 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG

PL Number: 15513/0168.

Date of preparation: 07 May 2024

Benylin Cold & Flu Max Strength Capsules (Paracetamol, Phenylephrine hydrochloride, Caffeine) Product Information

Presentation: Red/yellow capsule containing 500 mg Paracetamol, and 6.1 mg Phenylephrine HCl and 25 mg Caffeine.

Uses: For the relief of symptoms associated with the common cold and influenza, including relief of aches and pains, sore throat, headaches, fatigue and drowsiness, nasal congestion and lowering of temperature.

Dosage:

Adults, the elderly and children aged 16 years and over: 2 capsules every 4 hours, up to a maximum of 8 capsules in 24 hours. Leave 4-6 hours between doses. Patients should not use for longer than 3 days without consulting a doctor.

Contraindications:

Use in children under 16 years; Hypersensitivity to paracetamol or any of the other constituents. Caffeine: Should be given with care to patients with a history of peptic ulcer, Phenylephrine Hydrochloride: severe coronary heart disease and cardiovascular disorders, hypertension, hyperthyroidism, history of peptic ulcer. Within two weeks of taking or stopping MAOIs. Avoid in patients with prostatic enlargement.

Precautions:

Caution in severe renal or severe hepatic impairment, Raynaud's phenomenon and diabetes mellitus. Should not be taken alongside other paracetamol containing products. This medicine contains less than 1 mmol sodium (23 mg) per 2 capsules, that is to say essentially 'sodium-free'. Possible Interactions: metoclopramide, domperidone, cholestyramine, monoamine oxidase inhibitors (including moclobemide), sympathomimetic amines, beta-blockers and other antihypertensives (including debrisoquine, guanethidine, reserpine, methyldopa), tricyclic antidepressants, digoxin and cardiac glycosides, ergot alkaloids, warfarin and other coumarins, vasodilators and drugs which induce hepatic microsomal enzymes. Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been

associated with high anion gap metabolic acidosis, especially in patients with risk factors. See SPC for further details.
Pregnancy and lactation: Consult doctor before use. Product should be used in pregnancy only if the benefits outweigh this risk.
Side effects:
Paracetamol: Adverse effects of paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol. Very rare cases of serious skin reactions have been reported.
Caffeine: Nausea and insomnia have been noted.
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. Urinary retention has been reported (unknown frequency). This is most likely to occur in men with an enlarged prostate.
RRP (ex-VAT): 16 capsules £4.41.
Legal category: GSL.
PL Holder: Wrafton Laboratories Limited, Braunton, North Devon, EX33 2DL.
PL Number: 12063/0066.
Date of preparation: 17 APR 2023

Benylin Four Flu Tablets (Diphenhydramine Hydrochloride, Paracetamol, Pseudoephedrine Hydrochloride) Product Information

Presentation:
Orange, oval tablets containing 12.5mg diphenhydramine hydrochloride, 500mg paracetamol and 22.5mg pseudoephedrine hydrochloride per tablet.
Uses:
Symptomatic relief of colds and flu.
Dosage:
Adults and children over 16 years: two tablets up to four times daily (maximum of 8 tablets per day); Children aged 10 to 15 years: one tablet up to four times daily (maximum of 4 tablets per day).
Contraindications:
Benylin Four Flu Tablets should not be used in children under 10 years of age. This product is contraindicated in individuals with known hypersensitivity to diphenhydramine, paracetamol, pseudoephedrine, or to any of the product's excipients; cardiovascular disease including hypertension, diabetes mellitus, phaeochromocytoma, hyperthyroidism, closed angle glaucoma, severe acute or chronic kidney disease/renal failure. This product should not be used by individuals who are concomitantly taking beta blockers, or other sympathomimetic decongestants, and in individuals who are taking, or who have taken monoamine oxidase inhibitors (MAOIs) within the preceding 14 days. The concomitant use of MAOIs and pseudoephedrine-containing products may result in a rise in blood pressure and/or hypertensive crisis.

Precautions:
Benylin Four Flu Tablets may cause drowsiness. This product should not be used to sedate a child. Caution should be exercised in the presence of hepatic impairment (particularly if accompanied by cardiovascular disease), moderate to severe renal impairment, or occlusive vascular disease. The hazards of overdose are greater in individuals with non-cirrhotic alcoholic liver disease. Patients with thyroid disease who are receiving thyroid hormones should not take Benylin Four Flu Tablets unless directed by a physician. Patients with acute or chronic asthma, persistent or chronic cough such as in chronic bronchitis or emphysema, cough that is accompanied by excessive secretions, urinary retention, prostatic hyperplasia, and susceptibility to angle closure are advised to consult a physician before using this product. Benylin Four Flu Tablets should be discontinued if hallucinations, restlessness, or sleep disturbances occur.
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.
Some cases of ischaemic colitis have been reported with pseudoephedrine. This product should be discontinued, and medical advice sought if sudden abdominal pain, rectal bleeding, or other symptoms of ischaemic colitis develop.
Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. This product should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs.
Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported with the use of pseudoephedrine-containing products. The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure. Pseudoephedrine should be discontinued, and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances.
Do not use Benylin Four Flu Tablets with any other product containing diphenhydramine, including topical formulations used on large areas of skin. Both diphenhydramine and pseudoephedrine have been associated with central nervous system adverse events. Diphenhydramine may enhance the sedative effects of central nervous system depressants including alcohol, sedatives, opioid analgesics, antipsychotics, and tranquilizers. Alcoholic beverages should be avoided while taking this product. Avoid taking this product with other paracetamol-containing products as this could lead to overdose. Caution should be taken when paracetamol is used concomitantly with flucloxacillin as this has been associated with high anion gap metabolic acidosis (HAGMA), especially in patients with risks factors such as severe renal impairment, sepsis, malnutrition, and other sources of glutathione deficiency (e.g., chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.

Pregnancy and lactation:
This product should not be used during pregnancy unless the potential benefit of treatment to the mother outweighs any possible risk to the developing foetus. Use during lactation is not recommended.
Side effects:
Very Common: headache, somnolence, sedation.
Common: insomnia, nervousness, dizziness, paradoxical stimulation, psychomotor impairment, vision blurred, increased viscosity of bronchial secretions, dry mouth, gastrointestinal disorder, nausea, urinary retention (in men in whom prostatic enlargement could have been an important predisposing factor), asthenia
Uncommon: confusional state, irritability, tinnitus, rash
Rare: blood disorders, blood dyscrasias (including thrombocytopenia and agranulocytosis), hypersensitivity (cross-sensitivity may occur with other sympathomimetics), depression, sleep disorder, extrapyramidal disorder, seizure, tremor, palpitations, hypotension, liver disorder.
Not Known: anxiety, euphoric mood, excitability, hallucinations, paranoid delusions restlessness, cerebrovascular accident, paraesthesia, posterior reversible encephalopathy syndrome (PRES)/reversible cerebral vasoconstriction syndrome (RCVS), psychomotor hyperactivity, dysrhythmias, myocardial infarction/myocardial ischaemia, tachycardia, hypertension, dyspnoea, nasal dryness, ischaemic colitis, vomiting, angioedema, erythema, fixed eruption, pruritus, rash pruritic, serious skin reactions including acute generalised exanthematous pustulosis (AGEP), urticaria, dysuria, chest discomfort.
RRP (ex-VAT): 24 Tabs: £6.16.
Legal category: P.
PL holder: McNeil Products Ltd, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG, UK
PL Number: 15513/0058.
Date of preparation: 05 July 2024

Benylin Day and Night Tablets (Paracetamol, Diphenhydramine Hydrochloride, Pseudoephedrine Hydrochloride) Product Information

Presentation: Blue (Night) Tablet containing 500mg paracetamol and 25mg diphenhydramine hydrochloride HCl. White (Day) Tablet containing 500mg paracetamol and 60mg pseudoephedrine hydrochloride.
Uses: Relief of the symptoms associated with colds and influenza.
Dosage: Adults and children over 12 years: One white tablet every 4 to 6 hours (maximum of 3 tablets per day) during the day, one blue tablet at night. Under 12 years: not recommended.
Contraindications: This product is contraindicated in individuals with known hypersensitivity to paracetamol, diphenhydramine, pseudoephedrine, or to any of the product's excipients; cardiovascular disease including hypertension, diabetes mellitus,

phaeochromocytoma, hyperthyroidism, closed angle glaucoma, severe acute or chronic kidney disease/renal failure. This product should not be used by individuals who are concomitantly taking beta blockers, or other sympathomimetic decongestants, and in individuals who are taking, or who have taken monoamine oxidase inhibitors (MAOIs) within the preceding 14 days. The concomitant use of MAOIs and pseudoephedrine-containing products may result in a rise in blood pressure and/or hypertensive crisis.

Precautions:

May cause drowsiness. This product should not be used to sedate a child.

Diphenhydramine may enhance the sedative effects of central nervous system depressants including alcohol, sedatives, opioid analgesics, antipsychotics, and tranquilizers. Alcoholic beverages should be avoided while taking this product.

If any of the following occur, this product should be stopped: hallucinations, restlessness & sleep disturbances. Pseudoephedrine carries the risk of abuse and increased doses may ultimately produce toxicity. Continuous use can lead to tolerance resulting in an increased risk of overdosing. Do not exceed the recommended maximum dose and treatment duration.

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.

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.

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.

Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported with the use of pseudoephedrine-containing products. The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure. Pseudoephedrine should be discontinued, and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances.

Patients with the following conditions should be advised to consult a physician before using this product: acute or chronic asthma, a persistent or chronic cough such as occurs with chronic bronchitis or emphysema or where cough is accompanied by excessive secretions, difficulty in urination, urinary retention and/or prostatic hyperplasia, patients with thyroid disease who are receiving thyroid hormones.

This product should be used with caution in patients with susceptibility to angle-closure, severe hepatic impairment or moderate to severe acute or chronic kidney disease/renal failure (particularly if accompanied by cardiovascular disease), or occlusive vascular disease. Caution is advised if paracetamol is administered concomitantly with

flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition, and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.
Do not use with any other product containing diphenhydramine, including topical formulations used on large areas of skin. Taking this product with other paracetamol-containing products, could lead to overdose and should therefore be avoided. This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

Please refer to Summary of Product Characteristics for detailed information.

Pregnancy and lactation:

This product should not be used during pregnancy unless the potential benefit of treatment to the mother outweighs any possible risk to the developing foetus.
Breast-feeding: Use during lactation is not recommended.

Side effects:

Very common: headache, somnolence, sedation.

Common: insomnia, nervousness, dizziness, paradoxical stimulation, psychomotor impairment, vision blurred, increased viscosity of bronchial secretion, dry mouth, gastrointestinal disorder, nausea, urinary retention (in men in whom prostatic enlargement could have been an important predisposing factor), asthenia.

Uncommon: confusional state, irritability, tinnitus, rash.

Rare: blood disorders, blood dyscrasias (including thrombocytopenia and agranulocytosis) have been reported following paracetamol use but were not necessarily causally related to the drug, hypersensitivity (cross-sensitivity with other sympathomimetics), depression, sleep disorder, extrapyramidal disorder, seizure, tremor, palpitation, hypotension, liver disorder.

Not known: anxiety, euphoric mood, excitability, hallucinations, paranoid delusions, restlessness, cerebrovascular accident, paraesthesia, posterior reversible encephalopathy syndrome (PRES)/reversible cerebral vasoconstriction syndrome (RCVS), psychomotor hyperactivity, ischaemic optic neuropathy, dysrhythmias, myocardial infarction/myocardial ischaemia, tachycardia, hypertension, dyspnoea, nasal dryness, ischaemic colitis, vomiting, angioedema, erythema, fixed eruption, pruritus, rash pruritic, serious skin reactions including acute generalised exanthematous pustulosis (AGEP), urticaria, dysuria, chest discomfort.

Please refer to Summary of Product Characteristics for detailed information.

RRP (ex-VAT): 16 tablets £5.32.

Legal category: P.

PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK

PL Number: 15513/0108.

Date of preparation: 05 June 2024

Benylin Mucus Cough Max Honey & Lemon Flavour 100mg/5ml Syrup (Guaifenesin) Product Information

Presentation:
Clear yellow-brown coloured syrup containing 100 mg guaifenesin per 5 ml.
Uses:
For the symptomatic relief of productive cough in adults and adolescents of 12 years and above.
Dosage:
Adults and adolescents of 12 years and above: 10 ml (200mg guaifenesin) 4 times a day up to a maximum daily dose of 40ml (800mg guaifenesin)
Contraindications:
Hypersensitivity to the active substance or to any excipients.
Precautions:
Do not use in persistent or chronic cough, such as occurs with asthma, or where cough is accompanied by excessive secretions, unless directed by a physician. Caution in severe renal & hepatic impairment. The concomitant use of cough suppressants is not recommended. Contains approximately 2g of sucrose and 7g of glucose in each 10ml dose. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. Sucrose and glucose may be harmful to the teeth. This medicine contains 393 mg of alcohol (ethanol) in each 10 ml dose which is equivalent to 39.3 mg/ml. The amount in 10 ml of this medicine is equivalent to less than 10 ml beer or 4 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects. This medicinal product contains 41.1 mg sodium per 10 ml, equivalent to 2.054% of the WHO recommended maximum daily intake of 2 g sodium for an adult.
This medicinal product contains 20 mg of sodium benzoate in each 10 ml dose and 57.8 mg propylene glycol in each 10ml dose.
Pregnancy and Lactation:
Consult doctor. This product is not recommended during pregnancy and in women of childbearing potential not using contraception. Guaifenesin is excreted in breast milk in small amounts. There is insufficient information on the effects of guaifenesin in newborns/infants. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from using this product, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.
Side effects:
GI disorders (frequency not known): abdominal pain upper, diarrhoea, nausea, vomiting.
Immune System Disorders (frequency not known): hypersensitivity reactions including pruritus, urticaria and rash.
Please refer to Summary of Product Characteristics for detailed information

RRP (ex-VAT): 150ml: £6.58; 300ml: £8.74
Legal category: GSL
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, HP12 4EG, United Kingdom
PL Number: 15513/0377
Date of preparation: 21 Dec 2022

Benylin Herbal Chesty Coughs Sugar Free Syrup (Ivy leaf, Sorbitol) Product Information

Presentation: Brown, opalescent liquid containing 33 mg of extract (as dry extract) of Ivy leaf (*Hedera helix L.*) (DER 4-8:1). Extraction solvent ethanol 30% m/m and 2832 mg of Sorbitol per 4ml.
Uses: Used to relieve chesty coughs associated with the common cold, based on traditional use only.
Dosage: Adults, the elderly, and children aged 12 years and over: The recommended dose is 4 ml of syrup two to three times daily using the graduated measuring spoon provided.
Contraindications: Hypersensitivity to the active substance or to any of the excipients.
Precautions: Do not exceed the stated dose. The use of this product in children under 12 years of age is not recommended because data are not sufficient and medical advice should be sought. If dyspnoea, fever or purulent sputum occurs, a doctor should be consulted. If the symptoms worsen or persist longer than one week during the use of Benylin Herbal Chesty Coughs Sugar Free Syrup, a doctor or qualified healthcare practitioner should be consulted. Concomitant use with antitussives such as codeine or dextromethorphan is not recommended without medical advice. Caution is recommended in patients with gastritis or gastric ulcer.
Benylin Herbal Chesty Coughs Sugar Free Syrup contains sorbitol. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly. Each 4 ml of syrup contains 2832 mg of sorbitol (E 420). Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
Pregnancy and lactation: Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.
Side-effects: Gastrointestinal reactions (nausea, vomiting, and diarrhoea) have been reported. The frequency is not known. Allergic reactions (urticaria, skin rash, dyspnoea) have been reported. The frequency is not known.
RRP (ex-VAT): £5.20
Legal category: GSL.

PL holder: McNeil Products Limited, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG.
PL Number: THR 15513/0185
Date of preparation: 14 April 2022

Benylin Mucus Cough & Cold All in One Relief Tablets or Sudafed Mucus Relief Triple Action Cold & Flu Tablets (Paracetamol, Guaifenesin, Phenylephrine Hydrochloride) Product Information

Presentation:
Tablets containing 250mg paracetamol, 100mg guaifenesin, 5mg phenylephrine hydrochloride.
Uses:
Symptomatic relief of cold and flu, including aches and pains, headache, blocked nose, sore throat, chills, and chesty cough.
Dosage:
Adults and children 12 years and over: 2 tablets every 4 hours as required. Do not take more than 8 tablets in 24 hours. Children under 12 years: Not recommended.
Contraindications:
This product is contraindicated in individuals with known hypersensitivity to paracetamol, guaifenesin, phenylephrine, or to any of the product's excipients; hypertension, cardiovascular disorders, heart disease, severe hepatic impairment, severe renal impairment, hyperthyroidism, diabetes mellitus, phaeochromocytoma, glaucoma including closed angle glaucoma, urinary retention, and prostatic enlargement. This product should not be used by individuals who are concomitantly taking beta blockers or other sympathomimetics (such as decongestants, appetite suppressants, amphetamine-like psychostimulants), and in individuals who are taking, or who have taken monoamine oxidase inhibitors (MAOIs) within the preceding 14 days.
Precautions:
Benylin Mucus Cough & Cold All in One Relief Tablets or Sudafed Mucus Relief Triple Action Cold & Flu Tablets is not recommended for use in children under 12 years of age. Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended. Patients suffering from chronic cough or asthma, enlargement of the prostate gland, occlusive vascular disease and cardiovascular disease should consult a physician before taking the product. Patients should discontinue the product and consult a healthcare professional if cough lasts for more than 5 days or comes back, or is accompanied by a fever, rash, or persistent headache.Do not take this product while on other cough suppressants. Caution in patients with circulatory disorders, and prostatic hypertrophy. Use may give rise to

insomnia, nervousness, hyperpyrexia, tremor, and epileptiform convulsions. Long-term use not recommended.
Please refer to Summary of Product Characteristics for detailed information.
Pregnancy and Lactation: This product contains paracetamol and phenylephrine and should not be used during pregnancy or breastfeeding without medical advice.
Side effects:
Allergic reactions, angioedema, anaphylactic reactions, dyspnoea, nausea, vomiting, abdominal discomfort, diarrhoea, rash, urticaria, thrombocytopenia, agranulocytosis, Stevens Johnson syndrome, toxic epidermal necrolysis, bronchospasm, hepatic dysfunction, acute pancreatitis, nervousness, irritability, restlessness, excitability, headache, dizziness, insomnia, increased blood pressure, mydriasis, acute angle closure glaucoma, tachycardia, palpitations, hypersensitivity including cross-sensitivity with other sympathomimetics.
Dysuria and urinary retention have been reported (unknown frequency). This is most likely to occur in men with an enlarged prostate.
Please refer to Summary of Product Characteristics for detailed information.
Price (ex-VAT): 16s: £4.66.
Legal category: GSL.
PL holder: Wrafton Laboratories Limited (T/A Perrigo), Braunton, Devon EX33 2DL.
PL Number: 12063/0112.
Date of preparation: 17 April 2023

Benylin Herbal Cough & Cold Sugar Free Syrup (*Pelargonium*, Sorbitol, Maltitol) Product Information

Presentation:
A dark red syrup containing 20 mg of dry extract from Pelargonium root (*Pelargonium sidoides* DC and/or *Pelargonium reniforme* Curt., radix) per 2.5ml in extraction solvent ethanol 11% (m/m). Also contains 893mg of sorbitol (E 420) and 893mg of maltitol (E 965) per 2.5ml.

Uses:
Traditional herbal medicinal product used to relieve of symptoms associated with the common cold such as coughs, sore throat and blocked or runny nose. Based on traditional use only.

Dosage:
Adults, the elderly, and children over 12 years: Using the graduated measuring spoon provided, take 2.5ml, three times per day. Children between 6 to 12 years: Using the graduated measuring spoon provided, take 2.5ml, two times per day. Do not use for more than 10 days.

Contraindications:
Known hypersensitivity to *Pelargonium* root or any of the product's excipients. Not for use in patients with severe hepatic or renal disease and in patients with rare hereditary problems of fructose intolerance.

Precautions:

Do not exceed the stated dose. The use of this product in children under 6 years of age has not been established due to the lack of clinical data.
Hepatotoxicity and hepatitis were reported in association with the medicinal product. This product should be discontinued immediately in the occurrence of signs of hepatotoxicity, such as fatigue, anorexia, yellowing of the skin and eyes, severe stomach pain with nausea and vomiting, or dark urine. Consult with a qualified healthcare professional is advised. Moreover, the presence of any of following also warrant further consultation: worsening of symptoms, lack of improvement of symptoms after one week of intake, fever, shortness of breath, and blood in the sputum.
The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be considered. The content of sorbitol in medicinal products for oral use may also affect the bioavailability of other medicinal products for oral use administered concomitantly. Patients with rare hereditary problems of fructose intolerance should not take this medicine.
See SPC for further precautions.

Pregnancy and Lactation:

Safety during pregnancy and lactation has not been established. In the absence of sufficient data use during pregnancy and lactation is not recommended. Studies on the effects on fertility have not been performed.

Side effects:

Very rare: serious hypersensitivity reactions (e.g., swelling of the face, dyspnoea, and decrease in blood pressure), diarrhoea, epigastric discomfort, nausea or vomiting, dysphagia, mild nasal and gingival bleeding, dermatitis, rash, rash erythematous, exanthema, urticaria, pruritus of skin and mucous membranes.
Not known: Hepatotoxicity, hepatitis, liver dysfunction of different origin, dizziness, flushed skin.

RRP (ex-VAT): £ 6.50

Legal category: GSL

PL Holder: McNeil Products Limited 50 – 100 Holmers Farm Way High Wycombe Buckinghamshire HP12 4EG United Kingdom

PL Number: 15513/0186

Date of preparation: 21 March 2024