**Product Information for Benylin Chesty Coughs (Non-Drowsy) or Benylin Mucus Cough, Benylin Chesty Coughs (Original), Benylin Dry Coughs 7.5mg/5ml Syrup, Benylin Dry Coughs Night 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) or 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 3.5g, 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 to 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 5ml dose. The amount in 5ml 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. 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
*Please refer to Summary of Product Characteristics for detailed information.*
**RRP (ex-VAT):** *Benylin Chesty Coughs (Non-Drowsy)* 150 ml £6.58, 300 ml £8.74; *Benylin Mucus Cough* 150 ml £5.83, 300 ml £7.97.
**Legal category:** GSL.
**PL Holder:** McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG.
**PL Number(s):** PL 15513/0056.
**Date of prep:** 16 FEB 2022

## Benylin Chesty Coughs (Original) (diphenhydramine hydrochloride, levomenthol) Product Information

**Presentation:**
Red syrup containing 14 mg diphenhydramine hydrochloride and 2 mg levomenthol per 5 ml. This product also contains 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 (E 124) 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 5 ml. 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 5ml. 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.

**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.

*Please refer to Summary of Product Characteristics for detailed information.*

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

**Legal category:** P.

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

**PL Number(s):** PL 15513/0048.

**Date of prep:** 22 JUN 2023

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

**Presentation:**

Brown syrup containing 7.5 mg dextromethorphan hydrobromide per 5 ml. Each 5 ml also contains: sucrose 1.6 g, liquid glucose 2.38 g, sorbitol 325 mg, 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:* 10 ml 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. Fatal cases of dextromethorphan overdose have been reported very rarely.

Caution due to the following excipients:

- This product contains 2.38 g glucose and 1.6 g 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 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 5ml dose. The small amount of alcohol in this medicine will not have any noticeable effects.

**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.
*Please refer to Summary of Product Characteristics for detailed information.*
**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(s)**: PL 15513/0051
**Date of prep:** 08 JUL 2025

## Benylin Dry Coughs Night Syrup (diphenhydramine hydrochloride, dextromethorphan hydrobromide, levomenthol) Product Information

**Presentation:**
Clear red syrup containing 14 mg diphenhydramine hydrochloride, 6.5 mg dextromethorphan hydrobromide, and 2 mg levomenthol per 5ml. Each 5 ml 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 (or two 5 ml spoonfuls 4 times a day). Do not take more than 4 doses in 24 hours. Please take note that one dose is equal to two 5 ml spoonfuls.
**Contraindications:**
This product is contraindicated for use in children under 12 years of age and in individuals with known hypersensitivity to diphenhydramine, dextromethorphan, levomenthol or to any of the product's excipients. Dextromethorphan-containing products should not be used by individuals who are either currently taking, or who have taken monoamine oxidase inhibitors (MAOIs) within the preceding 14 days. Patients taking serotonin reuptake inhibitors (SSRIs), drugs which impair metabolism

of serotonin (including MAOIs), and CYP2D6 inhibitors, should not use this product. Concomitant use of dextromethorphan has been reported to induce a potentially life-threatening condition called serotonin syndrome, which includes mental-status changes, autonomic instability, neuromuscular abnormalities, and/or gastrointestinal symptoms. Discontinue this medicine immediately if serotonin syndrome is suspected. Dextromethorphan should not be given to patients in, or at risk of developing respiratory failure. This product contains 3.5 g glucose and 1 g sucrose per 5 ml; therefore, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption, or sucrase-isomaltase insufficiency should not take this medicine. It also contains Ponceau 4R (E124) red colouring and 0.48 mg benzyl alcohol per 5 ml, both of which may cause allergic reactions.

**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. This product should not be taken with any other cough and cold medicines. 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. It may also enhance the sedative effects of central nervous system depressants including alcohol, opioid analgesics, antipsychotics, sedatives, and tranquilizers. Do not use with any other product containing diphenhydramine including topical formulations used on large areas of skin.

Use of dextromethorphan with alcohol or other CNS depressants may increase the effects on the CNS and cause toxicity in relatively smaller doses. Fatal cases of dextromethorphan overdose have been reported very rarely. Caution should be exercised in atopic children due to histamine release. 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 should be exercised in patients who are slow metabolizers of CYP2D6 or use CYP2D6 inhibitors.

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.

Caution due to the following excipients:

- 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 5 ml; which 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. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding, or 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.

**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. There are no adequate and well-controlled studies in pregnant or breast-feeding women. It is not known whether dextromethorphan or its metabolites are excreted in breast milk or cross the placenta. However, 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. There are no adequate and well-controlled studies in pregnant women for menthol; however, menthol is excreted in breast milk.
**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
*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
*Please refer to Summary of Product Characteristics for detailed information.*
**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
**PL Number(s):** PL 15513/0053.
**Date of prep:** 14 MAY 2025

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

**Presentation:**
Red syrup containing 100mg 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, maximum of 40 ml 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 (E 124) 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 10mg of benzoate salt in each 10ml dose. This medicinal product may contain very trace amounts of glucose. A dose of 10ml of this medicine administered to a child 12 years of age and weighing 35kg would result in exposure to 10.9mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 1.81mg/100ml. A dose of 10ml of this medicine administered to an adult weighing 70kg would result in an exposure of 5.4mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 0.9mg/100 ml. (see Appendix 1 of report EMA/CHMP/43486/2018). For comparison, for an adult drinking a glass of wine or 500ml of beer, the BAC is likely to be about 50mg/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 (23mg) per 10ml 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:**

*Not known:* Abdominal pain upper, diarrhoea, nausea, vomiting, hypersensitivity reactions including pruritus, urticaria and rash.

*Please refer to Summary of Product Characteristics for detailed information*.

**RRP (ex-VAT):** 150 ml £6.58

**Legal category:** GSL.

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

**PL Number(s):** PL 15513/0165.
**Date of prep:** 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 14 mg diphenhydramine per 5 ml. Also contains 196.62 mg ethanol, 3498.7 mg glucose, 1005.7 mg sucrose, 0.25 mg Ponceau 4R, 18.53 mg sodium, and 10 mg sodium benzoate per 5 ml.
**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 is equivalent to 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 (E 124) red colouring which may cause

allergic reactions.
- This product contains 5 vol % ethanol (alcohol), i.e. up to 200 mg per 5 ml 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.

**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, arrhythmia, 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.
*Please refer to Summary of Product Characteristics for detailed information.*
**RRP (ex-VAT):** 150 ml £7.58
**Legal category:** P
**PL Holder:** McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG
**PL Number(s):** PL 15513/0050.
**Date of prep:** 25 JAN 2024

## Benylin Dry & Tickly Cough Syrup (glycerol, sucrose) Product Information

**Presentation:**
Liquid containing 0.75 ml glycerol and 1.707 g sucrose per 5 ml.
**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 to 5 years:* 5ml 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):** 150 ml £5.95, 300 ml £8.13.
**Legal category:** GSL.
**PL Holder:** McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG
**PL Number(s):** PL 15513/0142.
**Date of prep:** 10 MAR 2021

## Benylin Children's Chesty Coughs (guaifenesin) Product Information

**Presentation:**
Syrup containing 50 mg guaifenesin per 5 ml.
**Uses:**
Symptomatic relief of acute productive (chesty) coughs.
**Dosage:**
*Children 6 to 12 years:* 10 ml given four times daily, with a maximum daily dose of 40 ml.
**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 10ml 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 25.2mg benzoate salt in each 10ml dose. This medicine contains 0.1mg benzyl alcohol in each 10ml 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.
*Please refer to Summary of Product Characteristics for detailed information*.
**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
**PL Number(s)**: PL 15513/0052
**Date of prep:** 26 Oct 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 flavoured syrup containing glycerol 0.75 ml, sucrose 1.7 g per 5 ml.
**Uses:**
For the relief of irritating, tickling dry coughs and sore throats.
**Dosage:**
*Adults, elderly, and children over 5 years:* 10 ml. *Children 1 to 5 years:* 5 ml. 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.
**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 3.53 mg propylene glycol (E1520) in each 5ml dose, which is equivalent to 0.71 mg/ml. This medicine contains 10 mg sodium benzoate (E211) in each 5 ml which is equivalent to 2 mg/ml. This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially 'sodium-free'. This medicine contains 0.000053 mg benzyl alcohol in each 5 ml which is equivalent to 0.000011 mg/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.
**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.

*Please refer to Summary of Product Characteristics for detailed information*.
**RRP (ex-VAT):** 125 ml £4.08
**Legal category:** GSL.
**PL Holder:** McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG
**PL Number(s):** PL 15513/0392.
**Date of prep:** 24 DEC 2024

## Benylin Children's Night Coughs (diphenhydramine hydrochloride, levomenthol) Product Information

**Presentation:**
Syrup containing 7 mg diphenhydramine hydrochloride and 0.55 mg levomenthol per 5 ml. Each 5 ml also contains the following excipients: sorbitol (E 420) 2.53 g, ethanol 197 mg, sodium 16.47 mg, sodium benzoate (E 211) 25 mg.
**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 to 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 10ml of this medicine administered to a child 6 years of age and weighing 21kg would result in exposure to 18.8mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 3.13mg/100ml. For comparison, for an

adult drinking a glass of wine or 500ml 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 16.47mg sodium (main component of cooking/table salt) in each 5ml. This is equivalent to 0.82% of the recommended maximum daily dietary intake of sodium for an adult.
This product contains 2.53g 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 25mg sodium benzoate in each 5ml.

**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 100mg 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.

*Please refer to Summary of Product Characteristics for detailed information*.
**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
**PL Number(s):** PL 15513/0044.
**Date of prep:** 22 JUN 2023

## Benylin Infant's Cough Syrup (glycerol) Product Information

**Presentation:**
Syrup containing 0.75 ml glycerol per 5 ml (15%v/v).
**Uses:**
Relief of dry tickly coughs.
**Dosage:**
*Children aged 1 to 5 years:* two 5 ml spoonfuls (or 10 ml) given three to four times a day. *Children 3 months to 1 year:* one 5 ml spoonful given 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 5 ml, that is to say essentially 'sodium-free'. This medicine also contains 10 mg sodium benzoate (E 211) in each 5 ml which is equivalent to 2 mg/ml, and 18.24 mg propylene glycol (E 1520) in each 5 ml which is equivalent to 3.65 mg/ml.
**Pregnancy and Lactation:**
Not applicable.
**Side effects:**
Possible mild laxative effect.
*Please refer to Summary of Product Characteristics for detailed information*.
**RRP (ex-VAT):** 125ml £4.08
**Legal category:** GSL.
**PL Holder:** McNeil Products Ltd**,** 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG
**PL Number(s):** PL 15513/0168.
**Date of prep:** 28 NOV 2024

## Benylin Cold & Flu Max Strength Capsules (paracetamol, phenylephrine hydrochloride, caffeine) Product Information

**Presentation:**
Red/yellow capsule containing 500 mg paracetamol, 6.1 mg phenylephrine hydrochloride, 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 to 6 hours between doses. Patients should not use for longer than 3 days without consulting a doctor.

**Contraindications:**

This product is contraindicated for use in children under 16 years of age, in individuals with known hypersensitivity to paracetamol, caffeine, phenylephrine, or to any of the product's excipients. Benylin Cold & Flu Max Strength Capsules, hard contains caffeine and should be given with care to patients with a history of peptic ulcer. This product also contains phenylephrine, which is contraindicated in patients with severe coronary heart disease and cardiovascular disorders, hypertension, hyperthyroidism, This product should not be used by individuals who are either currently taking, or who have taken monoamine oxidase inhibitors (MAOIs) within the preceding 14 days.

**Precautions:**

Taking more than the recommended dose of Benylin Cold & Flu Max Strength Capsules, hard may cause liver damage. Concurrent intake of this product with other paracetamol-containing medicines can also lead to overdose and should therefore be avoided. Caution is advised in the use of this product in patients with severe hepatic impairment, severe renal impairment, or chronic alcohol use. Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. Patients suffering from enlargement of the prostate gland, Raynaud's phenomenon, and diabetes mellitus should consult a physician before taking the product. This medicine contains less than 1 mmol sodium (23mg) per 2 capsules, that is to say essentially 'sodium-free'. Paracetamol has known interactions with domperidone, metoclopramide, and cholestyramine. Please seek medical advice before taking paracetamol-caffeine-phenylephrine in combination with the following drugs: MAOIs (including moclobemide), sympathomimetics amines, vasodilators, beta-blockers, other hypertensives (including debrisoquine, guanethidine, reserpine, methyldopa), tricyclic antidepressants (e.g., amitriptyline), digoxin and cardiac glycosides, ergot alkaloids, warfarin and other coumarins, drugs that induce hepatic microsomal enzymes (e.g., alcohol, barbiturates, MAOIs, tricyclic antidepressants), and flucloxacillin.

**Pregnancy and Lactation:**

Consult doctor before use. This product should not be used in pregnancy unless benefits to the mother outweigh risk to foetus. No ill effects due to paracetamol use in human pregnancy using the recommended dosage have been shown; however, patients should follow the advice of their doctor regarding its use. Paracetamol is excreted in breast milk in low concentrations; however, available published data do not contraindicate breastfeeding. The half-life of caffeine during pregnancy is prolonged and may contribute to hyperemesis gravidarum (morning sickness). It also appears in breastmilk and irritability and poor sleeping pattern in the infant have

been reported. Due to the vasoconstrictive properties of phenylephrine, this medicine should be used with caution in patients with a history of pre-eclampsia. Phenylephrine may also reduce placental perfusion. There is no information on use of phenylephrine in lactation.

**Side effects:**

*Common:* nervousness, headache, dizziness, insomnia, increased blood pressure, nausea, vomiting, diarrhoea.

*Rare or very rare (paracetamol):* thrombocytopenia, agranulocytosis, anaphylaxis, cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson syndrome, toxic epidermal necrolysis, bronchospasm, hepatic dysfunction, acute pancreatitis

*Not known:* high anion gap metabolic acidosis, nervousness, anxiety, irritability, restlessness, excitability, dizziness, mydriasis, acute angle closure glaucoma (most likely to occur in those with closed angle glaucoma), tachycardia, palpitations, allergic reactions (e.g. rash, urticaria, allergic dermatitis), hypersensitivity reactions (including cross-sensitivity with other sympathomimetics), dysuria, urinary retention.

*Please refer to Summary of Product Characteristics for detailed information*.

**RRP (ex-VAT):** 16 capsules £4.41.

**Legal category:** GSL.

**PL Holder:** Wrafton Laboratories Limited, Wrafton, Braunton, North Devon, EX33 2DL.

**PL Number(s):** PL 12063/0066.

**Date of prep:** 01 MAR 2025

## Benylin Four Flu Tablets (diphenhydramine hydrochloride, paracetamol, pseudoephedrine hydrochloride) Product Information

**Presentation:**

Orange, oval biconvex film coated tablets containing 12.5 mg diphenhydramine hydrochloride, 500 mg paracetamol, and 22.5 mg pseudoephedrine hydrochloride per tablet.

**Uses:**

Symptomatic relief of symptoms associated with colds and flu, including relief of nasal congestion and congestion of mucous membranes of the upper respiratory tract, sneezing, runny nose, coughing, fever, headache, muscular aches and pains.

**Dosage:**

*Adults and children over 16 years:* two tablets up to four times daily (maximum of 8 tablets per day). Do not take more frequently than every 4 hours.

*Children aged 10 to 15 years:* one tablet up to four times daily (maximum of 4 tablets per day). Do not take more frequently than every 4 hours.

**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 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. 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. 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. 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. 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.

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at

therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. Avoid taking this product with other paracetamol-containing products as this could lead to overdose.
This medicine contains Sunset yellow (E110), which may cause allergic reactions. It also contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'.

**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. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency. The safety of pseudoephedrine in pregnancy has not been established. Diphenhydramine is known to cross the placenta and, therefore should only be used during pregnancy if considered essential by a doctor.
Pseudoephedrine is excreted in breast milk in small amounts, but the effect of this on breast-fed infants is not known. Paracetamol is also excreted in breast milk but not in a clinically significant amount. Maternal ingestion of therapeutic doses of paracetamol does not appear to present a risk to the infant. 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.

**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 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, 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, high anion gap metabolic acidosis.
*Please refer to Summary of Product Characteristics for detailed information.*

**RRP (ex-VAT):** 24's £6.16.
**Legal category:** P.
**PL Holder:** McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG
**PL Number(s):** PL 15513/0058.
**Date of prep:** 18 MAY 2025

# Benylin Day & Night Tablets (paracetamol, diphenhydramine hydrochloride, pseudoephedrine hydrochloride) Product Information

**Presentation:**
Blue (Night) Tablet containing 500 mg paracetamol and 25 mg diphenhydramine hydrochloride. White (Day) Tablet containing 500 mg paracetamol and 60 mg 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. Do not take the nighttime tablets during the day.
*Under 12 years:* not recommended.
**Contraindications:**
Benylin Day and Night Tablets 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:**
Benylin Day and Night 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 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 Day and Night Tablets unless directed by a physician. Patients with acute or chronic asthma, 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, susceptibility to angle-closure are advised to consult a physician before using this product.
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.
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. Do not use Benylin Day and Night 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.
Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism), who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. Avoid taking this product with other paracetamol-containing products as this could lead to overdose.
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

**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. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency. The safety of pseudoephedrine in pregnancy has not been established. Diphenhydramine is known to cross the placenta and, therefore should only be used during pregnancy if considered essential by a doctor.
Pseudoephedrine is excreted in breast milk in small amounts, but the effect of this on breast-fed infants is not known. Paracetamol is also excreted in breast milk but not in a clinically significant amount. Maternal ingestion of therapeutic doses of paracetamol does not appear to present a risk to the infant. 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.

**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, high anion gap metabolic acidosis.
*Please refer to Summary of Product Characteristics for detailed information.*
**RRP (ex-VAT):** 16's £5.33.
**Legal category:** P.
**PL Holder:** McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG
**PL Number(s):** PL 15513/0108.
**Date of prep:** 18 MAY 2025

## 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 (200 mg guaifenesin) 4 times a day up to a maximum daily dose of 40 ml (800 mg 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 2 g of sucrose and 7 g of glucose in each 10 ml 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 10ml of this medicine is equivalent to less than 10ml beer or 4ml 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 10ml 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, Buckinghamshire, HP12 4EG

**PL Number(s):** PL 15513/0377

**Date of prep:** 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 4 ml.

**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.

*Please refer to Summary of Product Characteristics for detailed information.*

**RRP (ex-VAT):** £5.42

**Legal category:** GSL.

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

**PL Number(s):** THR 15513/0185

**Date of prep:** 14 APR 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:**

White, capsule-shaped, film-coated tablet embossed with “PGP”, free from specks and blemishes, and containing 250 mg paracetamol, 100 mg guaifenesin, 5 mg 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. Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. 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.

**Pregnancy and Lactation:**

Consult a doctor before use. This product contains paracetamol and phenylephrine and should not be used during pregnancy or breastfeeding unless benefits to the mother outweigh risk to foetus. No ill effects due to paracetamol use in human pregnancy using the recommended dosage have been shown; however, patients should follow the advice of their doctor regarding its use. If clinically needed, paracetamol can be used during pregnancy; however, it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency. Paracetamol is excreted in breast milk in low concentrations; however, available published data do not contraindicate breastfeeding. The safety of guaifenesin in pregnancy and lactation has not been fully established but this constituent is not thought to be hazardous. Nevertheless, this product should only be used in pregnancy when considered essential by the doctor. Due to the vasoconstrictive properties of this drug, this medicine should be used with caution in patients with a history of pre-eclampsia. Phenylephrine may also reduce placental perfusion. There is no information on use of phenylephrine in lactation. While there is no information on phenylephrine use in lactation, phenylephrine is excreted in breast milk but not in a clinically significant amount.

**Side effects:**

*Common:* nervousness, irritability, restlessness, excitability, headache, dizziness, insomnia, increased blood pressure, nausea, vomiting, diarrhoea.

*Rare:* thrombocytopenia, agranulocytosis, anaphylaxis, cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson syndrome, toxic epidermal necrolysis, bronchospasm, hepatic dysfunction, acute pancreatitis

*Not known:* high anion gap metabolic acidosis, allergic reactions, angioedema, anaphylactic reactions, dyspnoea, nausea, vomiting, abdominal discomfort, rash, urticaria, mydriasis, acute angle closure glaucoma (most likely to occur in those with

closed angle glaucoma), tachycardia, palpitations, allergic reactions (e.g. rash, urticaria, allergic dermatitis), hypersensitivity reactions (including cross-sensitivity with other sympathomimetics), dysuria, urinary retention.
*Please refer to Summary of Product Characteristics for detailed information.*
**RRP (ex-VAT):** *Benylin Mucus Cough & Cold All in One Relief Tablets 16s:* £4.66; *Sudafed Mucus Relief Triple Action Cold & Flu Tablets 16s:* £4.83.
**Legal category:** GSL.
**PL Holder:** Wrafton Laboratories Limited (T/A Perrigo), Braunton, Devon EX33 2DL.
**PL Number(s):** PL 12063/0112.
**Date of prep:** 14 JUN 2025

## 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 2.5 ml in extraction solvent ethanol 11% (m/m). Also contains 893 mg of sorbitol (E 420) and 893mg of maltitol (E 965) per 2.5 ml.
**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 2.5 ml, three times per day. *Children between 6 to 12 years:* Using the graduated measuring spoon provided, take 2.5 ml, 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.

**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.
*Please refer to Summary of Product Characteristics for detailed information*.

**RRP (ex-VAT):** £ 5.42
**Legal category:** GSL
**PL Holder:** McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG
**PL Number(s):** THR 15513/0186
**Date of prep:** 21 MAR 2024