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

Adverse events should also be reported to McNeil Products Limited on 01344 864 042.

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

Presentation:
Brown syrup containing 7.5mg Dextromethorphan hydrobromide per 5ml.
Uses:
Relief of an unproductive cough.
Dosage:
Adults: 10ml four times daily.
Contraindications:
Use in children under 12 years. Known hypersensitivity to ingredients. With or within two weeks of receiving MAOIs. Patients in or at risk of respiratory failure. Patients taking SSRIs.
Precautions:
Not for use in patients with chronic or persistent cough, such as occurs with asthma or cough accompanied by excessive secretions. Caution in moderate to severe hepatic impairment. Caution in adolescents, young adults and in patients with a history of drug abuse or psychoactive substances. 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. Caution in atopic children due to histamine release. Patients with rare hereditary problems of fructose intolerance, glucosegalactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. Ethanol content should be considered in high-risk groups.
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, urticarial, insomnia, confusional state, convulsion, dizziness, psychomotor, hyperactivity, somnolence, respiratory depression, abdominal pain, diarrhoea, gastrointestinal disturbance, nausea, vomiting**.**
RRP (ex-VAT): 150 ml £5.43
Legal category: P.
PL Holder: McNeil Products Ltd, Foundation Park, Maidenhead, Berks, SL6 3UG.

PL Number: 15513/0051.
Date of preparation: 04 Jan 2017.

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

Presentation:
Liquid containing 0.75ml Glycerol and 1.93ml Liquid sugar per 5ml.
Uses:
Relief of tickly 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 recommended.
Contraindications:
Known hypersensitivity or intolerance to ingredients.
Precautions:
Diabetics should take note of the carbohydrate content of this product. Contains glucose, sucrose and small amounts of alcohol. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.
Pregnancy and Lactation:
The safety of this product during pregnancy and lactation has not been established. Consult doctor before use.
RRP (ex-VAT): 150ml £4.57, 300ml £6.89.
Legal category: GSL.
PL Holder: McNeil Products Ltd, Foundation Park, Maidenhead, Berks, SL6 3UG.
PL Number: 15513/0142.
Date of preparation: 16 Mar 2017

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 over 12 years: 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. Caution in severe renal & hepatic impairment. The concomitant use of cough suppressants is not recommended. Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. Contains 4.7 vol % alcohol; caution in alcoholism, pregnant and breastfeeding women, children and patients with liver disease or epilepsy.
Pregnancy and Lactation:
Consult doctor.
Side effects:
GI disorders (frequency not known): abdominal pain, diarrhea, 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: £5.09 300ml: £8.89
Legal category: GSL
PL Holder: McNeil Products Ltd, Foundation Park, Maidenhead, Berks, SL6 3UG.
PL Number: 15513/0377
Date of preparation: 07 July 2017

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

Presentation:
Red syrup containing 100 mg Guaifenesin and 1.1 mg Levomenthol per 5 ml.
Uses:
Symptomatic relief of cough.
Dosage:
Adults and children over 12 years: 10 ml four times daily.
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. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. Contains 5 vol % ethanol (alcohol). Can be harmful for those suffering from alcoholism. The ethanol content should be taken into account in pregnant or breastfeeding women, children and high-risk groups such as patients with liver disease or epilepsy. This product contains 16.42mg of sodium per 5ml. This should be taken into consideration by those on a controlled sodium diet. This product contains Ponceau 4R (E124) red colouring which may cause allergic reactions.
Pregnancy and Lactation:
Consult doctor.
Side effects:
Hypersensitivity reactions (hypersensitivity, pruritus and urticaria), rash. Abdominal pain upper, diarrhoea, nausea, vomiting
RRP (ex-VAT): 150ml £5.09; 300ml £7.41.
Legal category: GSL.
PL Holder: McNeil Products Ltd, Foundation Park, Maidenhead, Berks, SL6 3UG.
PL Number: 15513/0056.
Date of preparation: 28 Sep 2016.

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

Presentation:
Red syrup containing 14mg Diphenhydramine HCl and 2mg Levomenthol per 5ml.
Uses:
Relief of cough and associated congestive symptoms.
Dosage:
Adults and children over 12 years: 10ml four times daily.
Contraindications:
Use in children under 12 years. Known hypersensitivity to ingredients; chronic or persistent cough e.g. asthma, or cough accompanied by excessive secretions. With or within two weeks of receiving MAOIs.
Precautions:
May cause drowsiness, if affected, do not drive or operate machinery. Use with caution in moderate to severe renal or hepatic impairment or urinary retention. Do not use in narrow-angle glaucoma or prostatic hypertrophy. May potentiate effects of alcohol, codeine, antihistamines and other CNS depressants. May potentiate the effects of anticholinergics.
Pregnancy and lactation:
Consult doctor before use.
Side effects:
Drowsiness, dizziness, gastrointestinal disturbance, dry mouth, nose and throat, difficulty in urination or blurred vision. Infrequently: palpitations, tremor, convulsions, paraesthesia. Hypersensitivity reactions.
RRP (ex-VAT): 150ml £5.57; 300ml £8.15
Legal category: P.
PL Holder: McNeil Products Ltd, Foundation Park, Maidenhead, Berks, SL6 3UG.
PL Number: 15513/0048.
Date of preparation: 30 Jul 2014

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.
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. Known hypersensitivity to any actives or excipients. With or within two weeks of receiving MAOIs. Patients in or at risk of respiratory failure.
Precautions:
May cause drowsiness, if affected do not drive or operate machinery. Use with caution in moderate to severe renal or hepatic impairment. Do not use in narrow-angle glaucoma or symptomatic prostate hypertrophy. Use with caution in patients with a history of drug abuse or psychoactive substances. Use with caution in patients who are slow metabolizers of CYP2D6 or use CYP2D6 inhibitors. May potentiate effects of alcohol and other CNS depressants. May potentiate the effects of anticholinergics.
Pregnancy and lactation:
Consult doctor before use.
Side effects:
Drowsiness, dizziness, gastrointestinal disturbance, dry mouth, nose and throat, difficulty in urination or blurred vision, nausea, vomiting.
RRP (ex-VAT): 150 ml £5.43
Legal category: P.
PL Holder: McNeil Products Ltd, Foundation Park, Maidenhead, Berks, SL6 3UG.
PL Number: 15513/0053.
Date of preparation: 13 Dec 2016

Sudafed Sinus Max Strength Capsules Hard (Paracetamol 500mg, Caffeine 25mg, Phenylephrine 6.1mg) Product Information

Presentation:
Red/blue capsules containing paracetamol 500mg, caffeine 25mg, phenylephrine 6.1mg.
Uses:
Symptomatic relief of the pain and congestion of sinusitis, including relief of aches and pains, headache, nasal congestion and fever.
Dosage:
Adults and children over 16 years: 2 caps every 4-6 hours to a max of 4 doses in any 24 hours. Do not exceed 8 caps in any 24 hours. Dosage should not be continued for longer than 3 days without consulting a doctor.
Contraindications:
Use in children under 16 years; hypersensitivity, severe coronary heart disease and cardiovascular disorders, history of peptic ulcer, hypertension, hyperthyroidism, use with or within two weeks of receiving MAOIs.
Precautions:
Severe renal or severe hepatic impairment, Raynaud's Phenomenon, diabetes mellitus. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Should not be taken concomitantly with other paracetamol containing medicines. 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. See SPC for further details.
Pregnancy and Lactation:
Consult doctor before use.
Side effects:
Thrombocytopenia, agranulocytosis, anaphylaxis, cutaneous hypersensitivity reactions including skin rashes, angiodema and Stevens Johnson syndrome, cross-sensitivity with other sympathomimetics, toxic epidermal necrolysis, bronchospasm and hepatic dysfunction, nervousness, anxiety, irritability, restlessness, excitability, dizziness, headache, insomnia, increased blood pressure, nausea, vomiting, diarrhoea, 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), dysuria, urinary. See SPC for details.
RRP (ex VAT): 16s, £3.90
Legal category: GSL
PL Holder: Wrafton Laboratories Ltd, Wrafton, North Devon. EX33 2DL.
PL Number: PL 12063/0067
Date of prep: March 2017

Sudafed Sinus Pain Relief 200mg/6.1mg Tablets (Ibuprofen 200 mg, Phenylephrine hydrochloride 6.1 mg) Product Information

Presentation:
Green, round bi-convex sugar coated tablet.
Uses:
For the relief of symptoms of cold and flu with associated congestion, including aches and pains, headache, fever, sore throat, blocked nose and sinuses.
Dosage:
Adults, the elderly and children between 12 and 18 years: Two tablets every 8 hours, with or after food. Leave at least 4 hours between doses and do not exceed six tablets in any 24 hour period. A doctor should be consulted if the symptoms worsen or if the product is required for longer than 3 days in children between 12 and 18 years, or after 10 days in adults.
Contraindications:
Hypersensitivity to ibuprofen, aspirin, and other NSAIDS, phenylephrine hydrochloride or any of the excipients in the product. Hypertension and severe coronary heart disease. Active or history of recurrent peptic ulcer/haemorrhage. History of NSAID related gastrointestinal bleeding or perforation. Severe heart failure, renal failure or hepatic failure. Use with concomitant NSAIDs including cyclo-oxygenase-2 specific inhibitors. Patients being treated with monoamine oxidase inhibitors or within 14 days of ceasing such treatment. Patients with diabetes mellitus. Patients with closed angle glaucoma. Patients with hyperthyroidism. Patients suffering from prostatic enlargement. Patients suffering with phaeochromocytoma. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.
Precautions:
Use with caution in the elderly; women trying conceive; dehydrated children; history of GI disease or toxicity; concomitant medications increasing the risk of GI toxicity; hepatic or renal dysfunction; bronchial asthma or allergic disease; hypertension or heart failure; patients with increased risk factors for cardiovascular events; patients with occlusive vascular disease; SLE and mixed connective tissue disease. Should be used with caution in combination with: Anti-coagulants; Antihypertensives and diuretics; Corticosteroids; Anti-platelet agents and selective serotonin-reuptake inhibitors (SSRIs); Cardiac glycosides; Lithium; Methotrexate; Ciclosporin; Mifepristone; Tacrolimus; Zidovudine; Quinolone antibiotics; Sympathomimetic Amines; Beta-blockers and other Vasodilators; Anticholinergic Drugs; Cardiac Glycosides.
Pregnancy and Lactation:
Not recommended.
Side effects:
Uncommon: Hypersensitivity reactions with urticaria and pruritus; headache; tachycardia; cardiac arrhythmias; palpitations; hypertension; abdominal pain; nausea; dyspepsia; dizziness and tinnitus.
Rare: Diarrhoea; flatulence; constipation; vomiting; non-specific allergic reactions.
Very rare: Urinary retention in males; acute renal failure; papillary necrosis; severe forms of skin reactions such as bullous reactions; including Stevens Johnson syndrome; erythema multiforme and toxic epidermal necrolysis can occur; liver disorders; peptic

ulcer; perforation or gastrointestinal haemorrhage; melaena; haematemesis; ulcerative stomatitis; gastritis; exacerbation of ulcerative colitis and Crohn's disease; aseptic meningitis (singles cases); severe hypersensitivity reactions (anaphylaxis, angioedema or severe shock); haematopoietic disorders (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis).
Not known: Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome)
RRP (ex VAT): £4.58
Legal category: GSL
PL Holder: Galpharm Healthcare Limited, Wrafton, Braunton, Devon, EX33 2DL
PL Number: PL 16028/0149
Date of prep: 23 May 2018

Sudafed Sinus Pressure & Pain 200mg/30mg film-coated tablets (Pseudoephedrine HCL 30mg and Ibuprofen 200mg) Product Information

Presentation:
Yellow, round film-coated tablets containing pseudoephedrine HCL 30mg and Ibuprofen 200mg.
Uses:
Symptomatic treatment of nasal congestion associated with acute rhinosinusitis suspected to be of viral origin with headache and/or fever.
Dosage:
Adults and children over 15 years: 1 or 2 tablets every 6 hours, maximum 6 tablets per 24 hours. *Under 15 years*: Contraindicated.
Contraindications:
Hypersensitivity to ingredients, Pregnant women during the third trimester of pregnancy, Breast-feeding mothers, previous hypersensitivity reactions in response to acetylsalicylic acid or other NSAIDs, history of NSAID related gastrointestinal bleeding or perforation, history of recurrent peptic ulcer/haemorrhage, Cerebrovascular or other bleeding, haematopoietic abnormalities, severe hepatic insufficiency, severe renal failure, severe heart failure (NYHA Class IV), severe cardiovascular disorders, tachycardia, hyperthyroidism, diabetes, pheochromocytoma, coronary heart disease, history of stroke, closed angle glaucoma, risk of urinary retention, history of seizures, history of myocardial infarction, systemic lupus erythematosus, concomitant use of other vasoconstrictor agents, concomitant use of MAOIs or their use within the last two weeks of receiving MAOIs, concomitant use with NSAIDs and other COX2 inhibitors, combination with medicines that can lower the epileptic threshold, not to be taken in cases of asthma unless advised by a doctor.
Precautions:
Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur. Psychosis, Concomitant administration of antimigraine agents, systemic lupus erythematosus and mixed connective tissue disease, patients with urethroprostatic disorders, blood clotting disorder, risk of gastro-intestinal bleeding, ulceration or

perforation, history of gastrointestinal toxicity, caution with oral corticosteroids, anticoagulants, SSRIs or antiplatelet agents, heart failure, patients with chronically impaired renal or hepatic function, patients taking diuretics, patients who are hypovolaemic and the elderly, history of asthma, chronic headache, irritable bowel disease. Patients should consult a doctor if symptoms worsen. The maximum duration of treatment is 4 days for adults and 3 days for adolescents aged 15 years and older. Recommended dose and/or duration of treatment should not be exceeded. Increased doses may produce toxicity. Continuous use can lead to tolerance resulting in an increased risk of overdosing. Depression may follow rapid withdrawal. Overdosage may result in nausea and vomiting.

Pregnancy and Lactation:

Contraindicated during the third trimester. Given only if necessary and under supervision of physician during first and second trimester.

Side effects:

Common: Gastrointestinal discomfort, dyspepsia, abdominal pain, nausea, vomiting, flatulence, diarrhoea, constipation, minor gastrointestinal blood loss in rare cases leading to anaemia, insomnia, dry mouth, nausea. *Uncommon:* Hypersensitivity reactions with urticaria, pruritus and asthma attacks (with drop in blood pressure), central nervous disturbances such as headache, dizziness, sleeplessness, agitation, irritability or tiredness, visual disturbances, gastrointestinal ulcers sometimes with bleeding and/or perforation, gastritis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease, various skin rashes. *Rare:* Restlessness, tremor, hallucinations, Tinnitus, Exacerbation of asthma or hypersensitivity reaction with bronchospasm, Kidney-tissue damage and elevated uric acid concentrations in the blood. *Very rare:* Exacerbation of infectious inflammations, aseptic meningitis (stiffness of the neck, headache, nausea, vomiting, fever or disorientation, mixed connective tissue disease), haematopoietic disorders, severe generalised hypersensitivity reactions, psychotic reactions, depression, palpitations, heart failure, myocardial infarction, arterial hypertension, oesophagitis, pancreatitis, intestinal diaphragm-like stricture, hepatic dysfunction, hepatic damage, particularly in long term therapy, hepatic failure, acute hepatitis, bullous reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis, alopecia, severe skin infections and soft-tissue complications in a varicella infection, Increase in serum creatinine, oedemas, nephrotic syndrome, interstitial nephritis, acute renal insufficiency, rash, pruritus. *Not known:* Agitation, hallucination, anxiety, abnormal behaviour, haemorhagic stroke, ischemic stroke, convulsion, headache, palpitations, tachycardia, chest pain, arrhythmia, hypertension, thirst, vomiting, drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), urticaria, severe skin reaction including acute generalized exanthematous pustulosis (AGEP), hyperhidrosis, difficulty in micturition, euphoric mood, nervousness, somnolence, angioedema, urinary retention, dysuria.

RRP (ex VAT): 12s, £3.86; 24s, £5.95

Legal category: P

PL Holder: McNeil Products Ltd., Foundation Park, Roxborough Way, Maidenhead, SL6 3UG.

PL Number: PL 15513/0396

Date of prep: 12 September 2018

Sudafed Sinus-Ease 0.1% Nasal Spray (Xylometazoline Hydrochloride 0.1% w/v) Product Information

Presentation:
Metered dose bottle containing 0.1% w/v Xylometazoline hydrochloride as an aqueous solution.
Uses:
Symptomatic relief of nasal congestion associated with colds, influenza, sinusitis, and rhinitis and other upper respiratory tract allergies.
Dosage:
Adults and children 12 years and over: 1 spray into each nostril 2 – 3 times daily up to a maximum of 3 sprays daily*. Children under 12 years:* Not recommended.
Contraindications:
Hypersensitivity to ingredients, with or within 2 weeks of receiving MAOIs, hypophysectomy or surgery exposing dura mater.
Precautions:
Coronary artery disease, hypertension, diabetes mellitus, hyperthyroidism. Prolonged treatment may lead to reactive hyperemia of the nasal mucosa.
Pregnancy and Lactation:
Not recommended
Side effects:
Not Known: burning sensation mucosal, nasal discomfort, nasal dryness, nasal pruritus, rhinalgia, sneezing, rebound congestion. *Rare*: nausea and headache.
RRP (ex VAT): £3.95
Legal category: GSL
PL Holder: McNeil Products Ltd., Foundation Park, Roxborough Way, Maidenhead, SL6 3UG.
PL Number: PL 15513/0074
Date of prep: 09 May 2018

Sudafed Mucus Relief Day & Night Capsules (Paracetamol, Phenylephrine, Caffeine) Product Information

Presentation:
Red/yellow day capsules containing paracetamol 500mg, caffeine 25mg, phenylephrine 6.1mg; dark blue/light blue night capsules containing paracetamol 500mg, phenylephrine 6.1mg.
Uses:
Symptomatic relief of common cold and influenza, including aches and pains, sore throat, headache, fatigue and drowsiness (day capsule only), nasal congestion and fever.
Dosage: Adults and children over 16 years: 2 Red/ yellow caps every 4-6 hours during the day as required, followed by 2 dark blue/ light blue caps at bedtime. Leave at least 4-6 hours between doses. Do not take more than 8 caps in 24 hours or continue for longer than 3 days without seeing a doctor. Not recommended for children under 16 years of age.
Contraindications:
Hypersensitivity to the active ingredients or excipients, severe coronary heart disease and cardiovascular disorders, hypertension, hyperthyroidism, patients currently receiving or within 2 weeks of stopping therapy with MAOIs. History of peptic ulcer (day capsules only). Concomitant use with other paracetamol containing products.
Precautions:
Severe renal or severe hepatic impairment, Raynaud's Phenomenon, diabetes mellitus. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Keep out of the reach and sight of children. Possible interactions: metoclopramide, domperidone, colestyramine, anticoagulants, other sympathomimetics, vasodilators, beta-blockers, drugs which induce hepatic microsomal enzymes. See SPC for further details.
Pregnancy and lactation: Consult doctor before use.
Side-effects:
Nausea and insomnia (day capsules only). 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 with paracetamol. Phenylephrine may elevate blood pressure with headache, vomiting and rarely palpitations; tachycardia or reflex bradycardia; tingling and coolness of the skin. Rare reports of allergic reactions.
RRP (ex-VAT):16s (12 day/4 night): £4.16.
Legal category: GSL.
PL holder: Wrafton Laboratories Ltd, Wrafton, North Devon. EX33 2DL.
PL Number: 12063/0073.
Date of preparation: 26 Jan 2018

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:

Hypersensitivity to any of the ingredients, hepatic or severe renal impairment, hypertension, hyperthyroidism, diabetes, heart disease, glaucoma, including closed angle glaucoma, urinary retention, phaeochromocytoma, patients receiving other sympathomimetic drugs, or those taking tricyclic antidepressants or beta-blocking drugs, and those patients who are taking or have taken, within the last two weeks, monoamine oxidase inhibitors.

Precautions:

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 stop using 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. Not to take with a cough suppressant. 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. See SPC for further information. **Pregnancy and Lactation:**

This product 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, bronchospasm, hepatic dysfunction, acute pancreatitis, nervousness, irritability, restlessness, excitability, headache, dizziness, insomnia, increased blood pressure, mydriasis, acute angle closure glaucoma, tachycardia, and palpitations.

Price (ex-VAT): 16s: £4.16.

Legal category: GSL.

PL holder: Wrafton Laboratories Ltd (T/A Perrigo), Braunton, Devon. EX33 2DL.

PL Number: 12063/0112.

Date of preparation: 02 Mar 2016

Sudafed Mucus Relief 0.1% Nasal Spray (Xylometazoline Hydrochloride 0.1% w/v) Product Information

Presentation:
Metered dose bottle containing 0.1% w/v Xylometazoline hydrochloride as an aqueous solution.
Uses:
Symptomatic relief of nasal congestion associated with colds, influenza, sinusitis, and rhinitis and other upper respiratory tract allergies.
Dosage:
Adults and children 12 years and over: 1 spray into each nostril 2 – 3 times daily up to a maximum of 3 sprays daily. *Children under 12 years:* Not recommended.
Contraindications:
Hypersensitivity to ingredients, with or within 2 weeks of receiving MAOIs, hypophysectomy or surgery exposing dura mater.
Precautions:
Coronary artery disease, hypertension, diabetes mellitus, hyperthyroidism. Prolonged treatment may lead to reactive hyperemia of the nasal mucosa.
Pregnancy and Lactation:
Not recommended
Side effects:
Not Known: burning sensation mucosal, nasal discomfort, nasal dryness, nasal pruritus, rhinalgia, sneezing, rebound congestion. *Rare*: nausea and headache.
RRP (ex VAT): £3.95
Legal category: GSL
PL Holder: McNeil Products Ltd., Foundation Park, Roxborough Way, Maidenhead, SL6 3UG.
PL Number: PL 15513/0074
Date of prep: 09 May 2018

Sudafed Decongestant Tablets (Pseudoephedrine HCl 60mg) Product Information

Presentation:
Reddish-brown, round, biconvex film-coated tablets, with 'Sudafed' on one side. Tablets contain pseudoephedrine HCl 60mg.
Uses:
Symptomatic relief of allergic rhinitis, vasomotor rhinitis, common cold and influenza.
Dosage:
Adults and children over 12 years: 1 tablet every 4 – 6 hours up to 4 times a day.
Contraindications:
Hypersensitivity to ingredients, severe hypertension or coronary artery disease, with or within 2 weeks of receiving MAOIs.
Precautions:
Mild to moderate hypertension, renal impairment, severe hepatic impairment, heart disease, diabetes, hyperthyroidism, elevated intraocular pressure, prostatic enlargement. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Concomitant use of tricyclic antidepressants, bretylium, betanidine, guanethidine, debrisoquine, methyldopa, alpha and beta blockers, other sympathomimetic agents.
Pregnancy and Lactation:
Not recommended
Side effects:
Sleep disturbance, skin rash, urinary retention, rarely hallucinations.
RRP (ex VAT): 12s, £3.47
Legal category: P
PL Holder: McNeil Products Ltd., Foundation Park, Roxborough Way, Maidenhead, SL6 3UG.
PL Number: PL 15513/0024
Date of prep: January 2013

Sudafed Blocked Nose Capsules (Phenylephrine hydrochloride 12mg) Product Information

Presentation:
A yellow cap and body printed 'Sudafed 0593' in black.
Uses:
Relief of nasal congestion associated with colds and hayfever.
Dosage:
Adults and children over 12 years: one capsule up to 4 times a day*. Under 12 years:* not suitable.
Contraindications:
Hypersensitivity to ingredients, cardiovascular disease, diabetes, closed angle glaucoma, hyperthyroidism, prostatic enlargement, phaeochromocytoma, with or within 2 weeks of receiving MAOIs.
Precautions:
Occlusive vascular disease including Raynaud's phenomenon. Concurrent use of tricyclic antidepressants, other sympathomimetic drugs, vasodilators, beta blockers or enzyme inducers e.g. alcohol.
Pregnancy and Lactation:
Not recommended
Side effects:
Tachycardia, cardiac arrhythmias, palpitations, hypertension, nausea, vomiting, headache and occasionally urinary retention in males.
RRP (ex VAT): 12s, £2.67; 24s, £4.78
Legal category: GSL
PL Holder: McNeil Products Ltd., Foundation Park, Roxborough Way, Maidenhead, SL6 3UG.
PL Number: PL 15513/0125
Date of prep: March 2014

Sudafed Blocked Nose Spray (Xylometazoline Hydrochloride 0.1% w/v) Product Information

Presentation:
Metered dose bottle containing 0.1% w/v Xylometazoline hydrochloride as an aqueous solution.
Uses:
Symptomatic relief of nasal congestion associated with colds, influenza, sinusitis, and rhinitis and other upper respiratory tract allergies.
Dosage:
Adults and children 12 years and over: 1 spray into each nostril 2 – 3 times daily up to a maximum of 3 sprays daily*. Children under 12 years:* Not recommended.
Contraindications:
Hypersensitivity to ingredients, with or within 2 weeks of receiving MAOIs, hypophysectomy or surgery exposing dura mater.
Precautions:
Coronary artery disease, hypertension, diabetes mellitus, hyperthyroidism. Prolonged treatment may lead to reactive hyperemia of the nasal mucosa.
Pregnancy and Lactation:
Not recommended
Side effects:
Not Known: burning sensation mucosal, nasal discomfort, nasal dryness, nasal pruritus, rhinalgia, sneezing, rebound congestion. *Rare*: nausea and headache.
RRP (ex VAT): £3.95
Legal category: GSL
PL Holder: McNeil Products Ltd., Foundation Park, Roxborough Way, Maidenhead, SL6 3UG.
PL Number: PL 15513/0074
Date of prep: 09 May 2018

Sudafed Congestion & Headache Max Strength Capsules (paracetamol 500mg, caffeine 25mg, phenylephrine 6.1mg) Product Information

Presentation:
Red/blue capsules containing paracetamol 500mg, caffeine 25mg, phenylephrine 6.1mg.
Uses:
Symptomatic relief of the pain and congestion of sinusitis, including relief of aches and pains, headache, nasal congestion and fever.
Dosage: Adults and children over 16 years: 2 caps every 4-6 hours to a max of 4 doses in any 24 hours. Do not exceed 8 caps in any 24 hours. Dosage should not be continued for longer than 3 days without consulting a doctor.
Contraindications:
Use in children under 16 years; hypersensitivity, severe coronary heart disease and cardiovascular disorders, history of peptic ulcer, hypertension, hyperthyroidism, use with or within two weeks of receiving MAOIs.
Precautions:
Severe renal or severe hepatic impairment, Raynaud's Phenomenon, diabetes mellitus. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Should not be taken concomitantly with other paracetamol containing medicines. 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. See SPC for further details.
Pregnancy and lactation: Consult doctor before use.
Side-effects:
Thrombocytopenia, agranulocytosis, anaphylaxis, cutaneous hypersensitivity reactions including skin rashes, angiodema and Stevens Johnson syndrome, cross-sensitivity with other sympathomimetics, toxic epidermal necrolysis, bronchospasm and hepatic dysfunction, nervousness, anxiety, irritability, restlessness, excitability, dizziness, headache, insomnia, increased blood pressure, nausea, vomiting, diarrhoea, 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), dysuria, urinary retention. See SPC for details.
RRP (ex-VAT):16s: £3.90.
Legal category: GSL.
PL holder: Wrafton Laboratories Ltd, Wrafton, North Devon. EX33 2DL.
PL Number: 12063/0067.

Date of preparation: March 2017

Sudafed Congestion & Headache Relief Day & Night Capsules (paracetamol 500mg, caffeine 25mg, phenylephrine 6.1mg) Product Information

Presentation:
Red/yellow day capsules containing paracetamol 500mg, caffeine 25mg, phenylephrine 6.1mg; dark blue/light blue night capsules containing paracetamol 500mg, phenylephrine 6.1mg.

Uses:
Symptomatic relief of common cold and influenza, including aches and pains, sore throat, headache, fatigue and drowsiness (day capsule only), nasal congestion and fever.

Dosage: Adults and children over 16 years: 2 Red/ yellow caps every 4-6 hours during the day as required, followed by 2 dark blue/ light blue caps at bedtime. Leave at least 4-6 hours between doses. Do not take more than 8 caps in 24 hours or continue for longer than 3 days without seeing a doctor. Not recommended for children under 16 years of age.

Contraindications:
Hypersensitivity to the active ingredients or excipients, severe coronary heart disease and cardiovascular disorders, hypertension, hyperthyroidism, patients currently receiving or within 2 weeks of stopping therapy with MAOIs. History of peptic ulcer (day capsules only). Concomitant use with other paracetamol containing products.

Precautions:
Severe renal or severe hepatic impairment, Raynaud's Phenomenon, diabetes mellitus. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Keep out of the reach and sight of children. Possible interactions: metoclopramide, domperidone, colestyramine, anticoagulants, other sympathomimetics, vasodilators, beta-blockers, drugs which induce hepatic microsomal enzymes. See SPC for further details.

Pregnancy and lactation: Consult doctor before use.

Side-effects:
Nausea and insomnia (day capsules only). 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 with paracetamol. Phenylephrine may elevate blood pressure with headache, vomiting and rarely palpitations; tachycardia or reflex bradycardia; tingling and coolness of the skin. Rare reports of allergic reactions.

RRP (ex-VAT):16s (12 day/4 night): £4.16.

Legal category: GSL.

PL holder: Wrafton Laboratories Ltd, Wrafton, North Devon. EX33 2DL.

PL Number: 12063/0073.

Date of preparation: April 2017

Calprofen 100mg/5ml Oral Suspension Ibuprofen, Calprofen 100mg/5ml Ibuprofen Suspension and Calprofen Ibuprofen Suspension Product Information

Presentation:
Sachets and suspension containing 100mg Ibuprofen per 5ml. Calprofen 100mg/5ml Ibuprofen Suspension also contains maltitol syrup (E965), sodium methylhydroxybenzoate (E219), sodium propylhydroxybenzoate (E217), propylene glycol (E1520) and ethanol.

Uses:
Treatment of mild to moderate pain, headache, fever, post-immunisation pyrexia, symptoms of colds and flu and minor aches and pains.

Dosage:
For Pain and Fever: *Infants 3-6 months, weighing over 5kg:* One 2.5 ml dose may be taken 3 times in 24 hours; *Infants 6-12 months:* 2.5ml three times a day; *Children 1-2 years:* 2.5ml three to four times a day; *Children 3-7 years:* 5ml three to four times a day; *Children 8-12 years:* 10ml three to four times a day. Post-immunisation fever: 2.5ml (50mg) followed by one further 2.5ml (50mg) dose six hours later if necessary. No more than 2 doses in 24 hours. Leave 6 – 8 hours between dose.

Contraindications:
Hypersensitivity to ingredients, or to aspirin or other NSAIDs. Peptic ulceration/haemorrhage, perforation or GI bleeding. Concomitant use with NSAIDs. Severe hepatic, renal or heart failure. Women in the last trimester of pregnancy.

Precautions:
The elderly; women tying to conceive; dehydrated children; history of GI toxicity; concomitant medications increasing the risk of GI toxicity; hepatic or renal dysfunction; bronchial asthma or allergic disease; hypertension or heart failure; SLE and mixed connective tissue disease. Should be used with caution in patients receiving anticoagulants, antihypertensives and diuretics, corticosteroids, anti-platelet agents and SSRIs, cardiac glycosides, lithium, methotrexate, ciclosporin, mifepristone, tacrolimus, zidovudine, and quinolone antibiotics.

Pregnancy and lactation:
Not recommended.

Side effects:
Uncommon: Hypersensitivity reactions with urticaria and pruritus, abdominal pain, nausea and dyspepsia, Headache, various skin rashes.
Rare: diarrhoea, flatulence, constipation and vomiting.
Very rare: Severe hypersensitivity reactions. Symptoms could be: facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension (anaphylaxis, angioedema, or severe shock). Exacerbation of asthma and bronchospasm, peptic ulcer, perforation or gastrointestinal haemorrhage, melaena, haematemesis. Ulcerative stomatitis, gastritis, exacerbation of colitis and Crohn's disease. Acute renal failure, papillary necrosis especially in long term use, associated with increased serum urea and oedema. Liver disorders, haematopoietic disorders, severe forms of skin reactions such as bullous

reactions, including Stevens-Johnson Syndrome, erythema multiforme and toxic epidermal necrolysis.
Not known: Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome).
Price (ex-VAT): Sachets: 12 x 5ml: £3.45, Bottle 200ml: £5.04; 100ml: £3.16.
Legal category: Sachets: GSL. 200ml bottle: P. 100ml bottle: GSL.
PL holder: McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG.
PL numbers: Sachets: 15513/0158, 200ml: bottle 15513/0120. 100ml bottle**:** 15513/0147.
Date of preparation: 13 April 2018.

Calpol Infant Suspension (incl. Sachets), Calpol Sugar-Free Infant Suspension (incl. Sachets) (Paracetamol) Product Information:

Presentation:
Suspension containing 120mg Paracetamol per 5ml
Indication:
Treatment of mild to moderate pain and as an antipyretic. Can be used in many conditions including headache, toothache, earache, teething, sore throat, colds and influenza, aches and pains and post immunisation fever.
Dosage and Administration:
For the relief of fever after vaccinations at 2,3 and 4 months; 2.5ml up to 4 times a day starting at the time of vaccination. If your baby still needs this medicine two days after receiving the vaccine talk to you doctor or pharmacist. Dosage for the relief of pain and other causes of fever in babies aged 2-3 months (if your baby weighs over 4kg and was born after 37 weeks); 2.5ml. If necessary give a second dose after 4-6 hours. Dosage for Children over 3 months; Children 3 to 6 months: 2.5 ml. Children 6 to 24 months: 5 ml. Children 2 years to 4 years: 7.5 ml. Children 4 to 6 years: 10ml. Do not give more than 4 doses in 24 hours and leave at least 4 hours between doses.
Contraindications:
Hypersensitivity to paracetamol or other ingredients.
Precautions:
Caution in severe hepatic or renal impairment. Interactions with domperidone, metoclopramide, colestyramine, anticoagulants, alcohol, drugs that induce hepatic microsomal enzymes. Patients with rare hereditary problems of fructose intolerance should not take this medicine. Due to the presence of sucrose and sorbitol in the Infant Suspension, patients with glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine. Maltitol may have a mild laxative effect (Sugar-Free only). Parahydroxybenzoates and carmoisine may cause allergic reactions. Patients should be informed about the signs of serious skin reactions, and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.
Fertility, pregnancy and lactation: Consult doctor before use.
Side effects:

Very rarely hypersensitivity and anaphylactic reactions including skin rash. Very rare cases of skin reactions. Blood dyscrasias, chronic hepatic necrosis, papillary necrosis and low level transaminase elevations have been reported.

RRP (ex-VAT): 100ml bottle: £3.32; 200ml bottle: £5.48; 12 x 5ml sachets: £3.50; 20 x 5ml sachets (sugar free only): £5.63

Legal category: 200ml bottle: P; 100ml bottle: GSL; Sachets: GSL

PL Holder: McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG

PL Numbers: Calpol Infant suspension: 100ml bottle: 15513/0122; 200ml bottle: 15513/0004; Sachets: 15513/0154. Calpol Sugar-free Infant Suspension: 100ml bottle: 15513/0123; 200ml bottle: 15513/0006; Sachets:15513/0155

Date of Preparation: January 2016