Product Information for Sudafed Decongestant Liquid, Sudafed Decongestant Tablets, Sudafed Blocked Nose & Sinus Capsules, Sudafed Congestion & Headache Max Strength Capsules, Sudafed Sinus Pressure & Pain 200mg/30mg Film Coated Tablets, Sudafed Sinus Max Strength Capsules Hard, Sudafed Mucus Relief Triple Action Cold & Flu or Benylin Mucus Cough & Cold All in One Relief Tablets, Sudafed Congestion & Headache Relief Day & Night Capsules, Non-Drowsy Sudafed Decongestant Nasal Spray/ Sudafed Blocked Nose Spray/ Sudafed Mucus Relief 0.1% Nasal Spray/ Sudafed Sinus-Ease 0.1% Nasal Spray, and Sudafed Plus Blocked Nose 1mg/50mg/ml Nasal Spray Solution

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.

Sudafed Decongestant Liquid (pseudoephedrine hydrochloride) Product Information

Presentation:
Liquid containing 30mg per 5ml of pseudoephedrine hydrochloride.

Uses:
For the relief of nasal congestion and congestion of mucous membranes of the upper respiratory tract associated with the common cold.

Dosage:
Adults and children over 12 years: 10ml every 4 to 6 hours, up to 4 times a day.
Children 6 to 12 years: 5ml every 4 to 6 hours, up to 4 times a day

Contraindications
This product should not be used in children under 6 years. This product is contraindicated in individuals with known hypersensitivity to pseudoephedrine or to any of the 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:
Caution should be exercised when using the product in the presence of severe hepatic impairment or moderate to severe renal impairment, and in occlusive

vascular disease. Patients with the following conditions should be advised to consult a physician before using this product: difficulty in urination, urinary retention and/or prostatic hyperplasia, patients with thyroid disease who are receiving thyroid hormones. This product should be stopped if patients experience hallucinations, restlessness, sleep disturbances.
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.
Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs.
Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported with the use of pseudoephedrine-containing products. The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure. Pseudoephedrine should be discontinued, and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances.
This product contains the following excipients:

- 3g of sucrose per 5ml, which should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption, or sucrose-isomaltase insufficiency should not take this medicine.
- Methyl Hydroxybenzoate (E 218), which may cause possibly delayed allergic reactions.
- Ponceau 4R (E 124), which may cause allergic reactions.
- 3.73mg of propylene glycol in each 5ml.
- Less than 1mmol sodium (23mg) per 5ml, that is to say essentially ‘sodium free.’

Pregnancy and Lactation:
This product should not be used during pregnancy or lactation unless the potential benefit of treatment to the mother outweighs the possible risks to the developing foetus or breastfeeding infant.
Side effects:
Very common: headache
Common: insomnia, nervousness, dizziness, dry mouth, nausea
Not known: hypersensitivity (cross-sensitivity with other sympathomimetics), anxiety, euphoric mood, excitability, hallucinations, irritability, paranoid delusions, restlessness, sleep disorder, cerebrovascular accident, paraesthesia, posterior reversible encephalopathy syndrome (PRES)/reversible cerebral vasoconstriction syndrome (RCVS), psychomotor hyperactivity, somnolence, tremor, ischaemic optic neuropathy, dysrhythmias, myocardial infarction/myocardial ischaemia, palpitations, tachycardia, hypertension , ischaemic colitis, vomiting, , angioedema, pruritus, rash, severe skin reactions including acute generalised exanthematous pustulosis

(AGEP), dysuria, urinary retention (in men in whom prostatic enlargement could have been an important predisposing factor)
Please refer to Summary of Product Characteristics for detailed information.
RRP (ex VAT): 100ml £3.83
Legal category: P
PL Holder: McNeil Products Ltd., 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG, UK.
PL Number: PL 15513/0023
Date of prep: 16 May 2024

Sudafed Decongestant Tablets (pseudoephedrine hydrochloride) Product Information

Presentation:
Reddish-brown, round, biconvex film-coated tablets, with 'Sudafed' on one side. Tablets contain pseudoephedrine hydrochloride 60mg.

Uses:
Symptomatic relief of allergic rhinitis, vasomotor rhinitis, common cold and influenza.
Dosage:
Adults and children over 12 years: 1 tablet every 4 to 6 hours up to 4 times a day.
Contraindications:
This product is contraindicated in individuals with known hypersensitivity to pseudoephedrine or to any of its excipients; cardiovascular disease including hypertension, diabetes mellitus, phaeochromocytoma, hyperthyroidism, closed angle glaucoma, severe acute or chronic kidney disease/renal failure. This product is also contraindicated in individuals with concomitant use of other sympathomimetic decongestants, beta-blockers, or monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOI treatment. The concomitant use of MAOIs may cause a rise in blood pressure and/or hypertensive crisis.
Precautions:
This product contains lactose; patients with hereditary problems of galactose intolerance, total lactase deficiency, or glucose malabsorption should not take this medicine. Caution should be exercised when using the product in the presence of severe hepatic impairment or moderate to severe renal impairment and in occlusive vascular disease. Patients with difficulty in urination and/or enlargement of the prostate, or patients with thyroid disease who are receiving thyroid hormones should not take pseudoephedrine unless directed by a physician. This product should be stopped if hallucinations, restlessness, or sleep disturbances occur.
Pseudoephedrine has known interactions with the following medicinal products: moclobemide, antihypertensives such as bretylium, betanidine, guanethidine, debrisoquine, methyldopa, adrenergic neurone blockers and beta blockers, cardiac glycosides, ergotamine and methysergide, appetite suppressants and amphetamine-like psychostimulants, oxytocin, tricyclic antidepressants, and other anaesthetic agents.
Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. 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.

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

Side effects:
Very common: headache
Common: insomnia, nervousness, dizziness, dry mouth, nausea
Not known: hypersensitivity (cross-sensitivity with other sympathomimetics), anxiety, euphoric mood, excitability, hallucinations, irritability, paranoid delusions, restlessness, sleep disorder, cerebrovascular accident, paraesthesia, posterior reversible encephalopathy syndrome (PRES)/reversible cerebral vasoconstriction syndrome (RCVS), psychomotor hyperactivity, somnolence, tremor, ischaemic optic neuropathy, dysrhythmias, myocardial infarction/myocardial ischaemia, palpitations, tachycardia, hypertension, ischaemic colitis, vomiting, angioedema, pruritus, rash, severe skin reactions including acute generalised exanthematous pustulosis (AGEP), dysuria, urinary retention (in men in whom prostatic enlargement could have been an important predisposing factor)
Please refer to Summary of Product Characteristics for detailed information

RRP (ex VAT): 12s, £4.00
Legal category: P
PL Holder: McNeil Products Ltd., 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG, UK.
PL Number: PL 15513/0024
Date of prep: 16 May 2024

Sudafed Blocked Nose & Sinus Capsules (paracetamol, caffeine, phenylephrine) 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 lowering of temperature.
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. Avoid in patients with prostatic enlargement.
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. This medicine contains less than 1 mmol sodium (23 mg) per 2 capsules, that is to say essentially 'sodium-free'. Possible interactions: metoclopramide, domperidone, cholestyramine, monoamine oxidase inhibitors (including moclobemide), sympathomimetic amines, beta-blockers and other antihypertensives (including debrisoquine, guanethidine, reserpine, methyldopa), tricyclic antidepressants, digoxin and cardiac glycosides, ergot alkaloids, warfarin and other coumarins, vasodilators and drugs which induce hepatic microsomal enzymes. Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risk factors.
Pregnancy and lactation:
The product should be used in pregnancy only if the benefits outweigh this risk; moreover, it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency. Consult doctor before use.
Side-effects:
Thrombocytopenia, agranulocytosis, anaphylaxis, cutaneous hypersensitivity reactions including skin rashes, angioedema 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.
Please refer to Summary of Product Characteristics for detailed information.
RRP (ex-VAT):16s: £4.39
Legal category: GSL.
PL holder: Wrafton Laboratories Ltd, Wrafton, North Devon. EX33 2DL.
PL Number: 12063/0067.
Date of preparation: 27 Apr 2023

Sudafed Congestion & Headache Max Strength Capsules (paracetamol, caffeine, phenylephrine) 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 lowering of temperature.
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. Avoid in patients with prostatic enlargement.
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. This medicine contains less than 1 mmol sodium (23 mg) per 2 capsules, that is to say essentially 'sodium-free'. Possible interactions: metoclopramide, domperidone, cholestyramine, monoamine oxidase inhibitors (including moclobemide), sympathomimetic amines, beta-blockers and other antihypertensives (including debrisoquine, guanethidine, reserpine, methyldopa), tricyclic antidepressants, digoxin and cardiac glycosides, ergot alkaloids, warfarin and other coumarins, vasodilators and drugs which induce hepatic microsomal enzymes. Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risk factors.
Pregnancy and lactation:
The product should be used in pregnancy only if the benefits outweigh this risk; moreover, it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency. Consult doctor before use.
Side-effects:
Thrombocytopenia, agranulocytosis, anaphylaxis, cutaneous hypersensitivity reactions including skin rashes, angioedema 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.
Please refer to Summary of Product Characteristics for detailed information.
RRP (ex-VAT):16s: £4.39
Legal category: GSL.
PL holder: Wrafton Laboratories Ltd, Wrafton, North Devon. EX33 2DL.
PL Number: 12063/0067.
Date of preparation: 27 Apr 2023

Sudafed Sinus Pressure & Pain 200mg/30mg film-coated tablets (pseudoephedrine hydrochloride and ibuprofen) Product Information

Presentation:
Yellow, round film-coated tablets containing pseudoephedrine hydrochloride 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. The maximum duration of treatment is 4 days for adults and 3 days for adolescents aged 15 years and older. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.
Contraindications:
This product is contraindicated in children under 15 years, in individuals with known hypersensitivity to ibuprofen, phenylephrine, acetylsalicylic acid, other NSAIDs, or to any of the product's excipients; in pregnant women during the third trimester of pregnancy and breast-feeding mothers; in individuals with a history of NSAID-related gastrointestinal bleeding or perforation, active or history of recurrent peptic ulcer/haemorrhage; cerebrovascular or other bleeding, unexplained haematopoietic abnormalities; severe hepatic impairment, severe acute or chronic kidney disease / renal failure, severe heart failure (NYHA Class IV); severe cardiovascular disorders, a history of myocardial infarction, coronary heart disease (heart disease, hypertension, angina pectoris), tachycardia; a history of stroke or presence of risk factors for stroke; hyperthyroidism, diabetes mellitus, phaeochromocytoma, closed-angle glaucoma, risk of urinary retention related to urethroprostatic disorders; history of seizures; systemic lupus erythematosus. This product should also not be used by individuals who are concomitantly taking oral or intranasal vasoconstrictor agents (e.g., nasal decongestants such as phenylpropanolamine, phenylephrine and ephedrine), methylphenidate, as well as by individuals who are taking, or who have taken monoamine oxidase inhibitors (MAOIs) within the preceding 14 days.
Precautions:
Concomitant use of Sudafed Sinus Pressure & Pain 200mg/30mg film-coated tablets with NSAIDs including COX-2 selective inhibitors, and in combination with medicines that can lower the epileptogenic threshold, should not be taken in cases of asthma unless advised by a doctor. If signs and symptoms such as fever (pyrexia), erythema, or many small pustules are observed, administration of this medicine should be discontinued, and appropriate measures taken if needed. Psychosis, concomitant administration of antimigraine agents, hypertension, systemic lupus erythematosus and mixed connective tissue disease, neurological symptoms, 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, history of gastrointestinal disease, 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. Patients should consult a doctor if

symptoms worsen. Recommended dose and/or duration of treatment should not be exceeded since increased doses may result in 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.
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.
Ibuprofen may cause a severe allergic reaction, especially in patients allergic to acetylsalicylic acid. Symptoms may include hives, facial swelling, asthma (wheezing), shock, skin reddening, rash or blisters with or without pyrexia or erythema. Severe cutaneous adverse reactions (SCARs) including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), and acute generalized exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported in association with the use of ibuprofen.
Kounis syndrome, defined as cardiovascular symptoms secondary to an allergic or hypersensitive reaction associated with constriction of coronary arteries, has been reported in patients treated with Sudafed Sinus Pressure & Pain 200mg/30mg film-coated tablets; this can potentially lead to myocardial infarction. Prolonged use of ibuprofen-containing products at higher than recommended doses or overdose may result in renal tubular acidosis and hypokalaemia.
Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported with the use of pseudoephedrine-containing products. The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure. Pseudoephedrine should be discontinued, and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances. This medicine can mask symptoms of infection, which may lead to delayed initiation of appropriate treatment and thereby worsening the outcome of the infection. This has been observed in bacterial community acquired pneumonia and bacterial complications to varicella. When this medicine is administered for fever or pain relief in relation to infection, monitoring of infection is advised. In non-hospitals settings, the patient should consult a doctor if symptoms persist or worsen. This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say, “sodium free”.

Pregnancy and Lactation:

Pregnancy: Contraindicated during the third trimester. Given only if necessary and under supervision of physician during first and second trimester. Lactation: Contraindicated during lactation. See SPC for further information.

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, 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, severe cutaneous adverse reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell syndrome), erythema multiforme, exfoliative dermatitis, 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, haemorrhagic stroke, ischemic stroke, convulsion, headache, PRES, RCVS, palpitations, tachycardia, chest pain, arrhythmia, hypertension, thirst, vomiting, DRESS syndrome, urticaria, severe skin reaction including AGEP, hyperhidrosis, difficulty in micturition, euphoric mood, nervousness, somnolence, angioedema, urinary retention, dysuria, ischaemic optic neuropathy, photosensitivity reactions, Kounis syndrome.
Please refer to Summary of Product Characteristics for detailed information.
See SPC for further information.
RRP (ex VAT): 12s, £4.49; 24s, £6.95
Legal category: P
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK
PL Number: PL 15513/0396
Date of prep: 20 Feb 2025

Sudafed Sinus Max Strength Capsules Hard (paracetamol, caffeine, phenylephrine) 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. Avoid in patients with prostatic enlargement.
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. This medicine contains less than 1 mmol sodium (23mg) per 2 capsules, that is to say essentially 'sodium-free'. Possible interactions: metoclopramide, domperidone, cholestyramine, monoamine oxidase inhibitors (including moclobemide), sympathomimetic amines, beta-blockers and other antihypertensives (including debrisoquine, guanethidine, reserpine, methyldopa), tricyclic antidepressants, digoxin and cardiac glycosides, ergot alkaloids, warfarin and other coumarins, vasodilators and drugs which induce hepatic microsomal enzymes. Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risk factors.
Pregnancy and Lactation:
The product should be used in pregnancy only if the benefits outweigh this risk; moreover, it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency. Consult doctor before use.
Side effects: Thrombocytopenia, agranulocytosis, anaphylaxis, cutaneous hypersensitivity reactions including skin rashes, angioedema 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.
Please refer to Summary of Product Characteristics for detailed information.
RRP (ex VAT): 16s, £4.39
Legal category: GSL
PL Holder: Wrafton Laboratories Ltd, Wrafton, North Devon. EX33 2DL.
PL Number: PL 12063/0067
Date of prep: 27 Apr 2023

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

Presentation:
Tablets containing 250mg paracetamol, 100mg guaifenesin, 5mg phenylephrine hydrochloride.

Uses:
Symptomatic relief of cold and flu, including aches and pains, headache, blocked nose, sore throat, chills and chesty cough.
Dosage:
Adults and children 12 years and over: 2 tablets every 4 hours as required. Do not

take more than 8 tablets in 24 hours. *Children under 12 years:* Not recommended.

Contraindications:

This product is contraindicated in individuals with known hypersensitivity to paracetamol, guaifenesin, phenylephrine, or to any of the product's excipients; hypertension, cardiovascular disorders, heart disease, severe hepatic impairment, severe renal impairment, hyperthyroidism, diabetes mellitus, phaeochromocytoma, glaucoma including closed angle glaucoma, urinary retention, and prostatic enlargement. This product should not be used by individuals who are concomitantly taking beta blockers or other sympathomimetics (such as decongestants, appetite suppressants, amphetamine-like psychostimulants), and in individuals who are taking, or who have taken monoamine oxidase inhibitors (MAOIs) within the preceding 14 days.

Precautions:

Benylin Mucus Cough & Cold All in One Relief Tablets or Sudafed Mucus Relief Triple Action Cold & Flu Tablets is not recommended for use in children under 12 years of age. Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended. Patients suffering from chronic cough or asthma, enlargement of the prostate gland, occlusive vascular disease and cardiovascular disease should consult a physician before taking the product. Patients should discontinue the product and consult a healthcare professional if cough lasts for more than 5 days or comes back, or is accompanied by a fever, rash or persistent headache. Do not take this product while on other cough suppressants. Caution in patients with circulatory disorders, and prostatic hypertrophy. Use may give rise to insomnia, nervousness, hyperpyrexia, tremor, and epileptiform convulsions. Long-term use is not recommended.

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, Stevens Johnson syndrome, toxic epidermal necrolysis, bronchospasm, hepatic dysfunction, acute pancreatitis, nervousness, irritability, restlessness, excitability, headache, dizziness, insomnia, increased blood pressure, mydriasis, acute angle closure glaucoma, tachycardia, palpitations, hypersensitivity including cross-sensitivity with other sympathomimetics.

Dysuria and urinary retention have been reported (unknown frequency). This is most likely to occur in men with an enlarged prostate.

Please refer to Summary of Product Characteristics for detailed information.

Price (ex-VAT): 16s: £4.64

Legal category: GSL.

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

PL Number: 12063/0112.

Date of preparation: 17 Apr 2023

Sudafed Congestion & Headache Relief Day & Night Capsules (Paracetamol, Caffeine, Phenylephrine Hydrochloride) Product Information

Presentation:
Red/yellow day capsules containing paracetamol 500mg, caffeine 25mg, phenylephrine hydrochloride 6.1mg; dark blue/light blue night capsules containing paracetamol 500mg, phenylephrine hydrochloride 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, elderly, and children aged 16 years and over: two red/yellow capsules every 4 to 6 hours during the day as required, followed by two dark blue/light blue capsules at bedtime. Leave at least 4 to 6 hours between doses. Do not take more than 8 capsules (or 4 doses) in 24 hours. *Children under 16 years:* not recommended. *Frail and immobile elderly patients:* reduced dose or frequency is recommended; please seek medical advice before use.

Contraindications:
This product is contraindicated in individuals with known hypersensitivity to paracetamol, caffeine, phenylephrine, or to any of the product's excipients; hypertension, cardiovascular disorders, severe hepatic impairment, severe renal impairment, hyperthyroidism, diabetes mellitus, phaeochromocytoma, angle closure glaucoma, 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:
Sudafed Congestion & Headache relief Day & Night Capsules is not recommended for use in children under 16 years of age. Paracetamol-containing drugs should be given with caution to patients diagnosed with the following conditions and are advised to seek medical advice before using this product: renal impairment and mild or moderate hepatic impairment, chronic alcoholism, Gilbert's Syndrome (familial non-haemolytic jaundice), glucose-6-phosphate dehydrogenase deficiency, haemolytic anaemia, glutathione deficiency, malnutrition, dehydration, urinary retention, occlusive vascular disease (e.g., Raynaud's syndrome). Moreover, precaution should be observed in patients with asthma who are also sensitive to acetylsalicylic acid since mild bronchospasms have been reported in association with paracetamol (cross-reaction).
Hepatotoxicity at therapeutic doses of paracetamol has been reported, with a higher risk for hepatotoxicity observed in individuals weighing less than 50kg, renal and hepatic impairment, chronic alcoholism, acute and chronic malnutrition, and concomitant intake of hepatotoxic drugs. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.
Possible interactions with Sudafed Congestion & Headache Relief Day & Night Capsules may occur with the following: other paracetamol-containing products, cold and flu medicines, floxacillin, metoclopramide, domperidone, cholestyramine,

warfarin and other coumarins, alcohol, barbiturates, probenecid, other sympathomimetics, vasodilators, beta-blockers, digoxin and cardiac glycosides, and ergot alkaloids.
Excessive intake of caffeinated products such as coffee, tea, and some canned drinks, should be avoided while taking this product. Caution should be observed when this product is given to patients with a history of peptic ulcer.
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say it is essentially 'sodium-free'.
Pregnancy and lactation:
This product contains phenylephrine; this ingredient is contraindicated during pregnancy.
Side-effects:
Rare: allergies (not including angioedema), allergic reactions, mydriasis, acute angle closure glaucoma, palpitations, tachycardia, reflex bradycardia, rash, urticaria, allergic dermatitis.
Very rare: blood dyscrasias (e.g., thrombocytopenia, leukopenia, pancytopenia, neutropenia, agranulocytosis), anaphylaxis, bronchospasms in patients sensitive to aspirin and other NSAIDs, hepatic dysfunction, cutaneous hypersensitivity reactions (e.g., skin rashes, pruritus, sweating, purpura, urticaria, angioedema), toxic epidermal necrolysis (TEN), drug-induced dermatitis, Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), sterile pyuria.
Not known: insomnia, nervousness, dizziness, nausea, headache, elevated blood pressure, cardiac arrhythmias, vomiting, diarrhoea, tingling and coolness of the skin, dysuria, urinary retention.
Please refer to Summary of Product Characteristics for detailed information.
RRP (ex-VAT):16s (12 day/4 night): £4.64
Legal category: GSL.
PL holder: Wrafton Laboratories Ltd, Wrafton, North Devon. EX33 2DL
PL numbers: 12063/0073
Date of preparation: 05 Jun 2024

Non-Drowsy Sudafed Decongestant Nasal Spray/ Sudafed Blocked Nose Spray/ Sudafed Mucus Relief 0.1% Nasal Spray/ Sudafed Sinus-Ease 0.1% Nasal Spray (xylometazoline hydrochloride) 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. Patients with long QT syndrome. Prolonged treatment may lead to reactive hyperaemia of the nasal mucosa. This medicine contains 1.96 mg benzalkonium chloride in each 10 ml, and 2.94 mg benzalkonium chloride in each 15 ml, which is equivalent to 0.196 mg/ml of product. Benzalkonium chloride may cause irritation or swelling inside the nose, especially if used for a long time. Long-term use may cause oedema 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. Uncommon: Epistaxis *Rare*: nausea and headache.

Please refer to Summary of Product Characteristics for detailed information.

RRP (ex VAT): £4.84

Legal category: GSL

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

PL Number: PL 15513/0074

Date of prep: 22 Dec 2022

Sudafed Plus Blocked Nose 1mg/50mg/ml Nasal Spray Solution (xylometazoline hydrochloride and dexpanthenol) Product Information

Presentation:

Spray pump bottle containing 10ml of a clear, colourless to slightly yellowish solution. Each 1ml of nasal spray contains 1mg xylometazoline hydrochloride and 50mg dexpanthenol.

Uses:

Symptomatic relief of nasal congestion associated with the common cold, influenza, sinusitis allergic and non-allergic rhinitis (vasomotor rhinitis), other upper respiratory tract allergies.

Dosage:

Adults and children 12 years and over: One spray into each nostril up to 3 times a day, Maximum daily dose: 3 sprays in 24 hours. Use for more than 7 consecutive days is not recommended. *Children under 12 years:* Do not give to children under 12 years of age.

Contraindications:

Contraindicated in children under 12 years of age. Also contraindicated in individuals with the following conditions: hypersensitivity to the active substances or to any of the excipients listed, dry inflammation of the nasal mucosa (rhinitis sicca), taking or have taken monoamine oxidase inhibitors within the preceding two weeks, and with a history of transsphenoidal hypophysectomy or other surgical interventions which

expose the dura mater.

Precautions:

Use with caution due to minimal systemic absorption with topically applied imidazoline sympathomimetics such as xylometazoline. Use of this product is recommended only after a careful assessment of the risks and benefits for cases of increased intraocular pressure, especially narrow-angle glaucoma, serious heart and circulatory diseases (e.g. coronary heart disease, hypertension), phaeochromocytoma, metabolic disorders (e.g., hyperthyroidism, diabetes), porphyria, and prostate hyperplasia. Patients with long QT syndrome treated with xylometazoline may be at increased risk of serious ventricular arrhythmias.
Use during chronic rhinitis may only be carried out under medical supervision.
Prolonged treatment may lead to reactive hyperaemia of the nasal mucosa. Direct contact of the medicinal product with the eyes should be avoided.

Interactions: Concomitant use with other sympathomimetics, antihypertensive agents, and medicines which potentially increase blood pressure should be avoided.

Pregnancy and Lactation:

Not recommended

Side effects:

Uncommon: Hypersensitivity reaction (angioedema, skin rash, pruritus),
Rare: palpitations, tachycardia, hypertension.
Very rare: restlessness, insomnia, hallucinations, fatigue (drowsiness, sedation), headache, convulsions, arrhythmias, rebound congestion, nosebleed
Not Known: Sneezing, burning and dryness of the nasal mucosa.
Please refer to Summary of Product Characteristics for detailed information.

RRP (ex VAT): £5.84

Legal category: P

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

PL Number: PL 15513/0407

Date of prep: 03 Aug 2022