

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 30mg/5ml) 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 4-6 hours up to 4 times a day. Children 6- 12 years: 5ml every 4-6 hours up to 4 times a day

Contraindications

This product is contraindicated in individuals with known hypersensitivity to pseudoephedrine or to any of the excipients. Children under 6 years, hypersensitivity, cardiovascular disease including hypertension, with or within 2 weeks of receiving MAOIs and/or RIMAs, diabetes mellitus, phaeochromocytoma, hyperthyroidism, closed angle glaucoma, severe renal impairment, concomitant use of other sympathomimetic decongestants or beta blockers. The concomitant use of MAOIs may cause a rise in blood pressure and/ or hypertensive crisis.

Precautions:

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. 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. 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. Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs. There have been rare cases of posterior reversible encephalopathy syndrome (PRES)/ reversible cerebral vasoconstriction syndrome (RCVS) reported with sympathomimetic drugs, including pseudoephedrine. Each 5 ml of this medicine contains 3.5 g of sucrose. 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 methyl hydroxybenzoate (E218) and therefore may cause allergic reactions (possibly delayed). This medicine contains Ponceau 4R (E124) and therefore may cause allergic reactions. This medicine contains 3.73 mg propylene glycol in each 5ml. This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, 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 may occur 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/myocardia 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)

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: 8th September 2021

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. This product is contraindicated in individuals who are concomitantly taking other sympathomimetic decongestants and individuals taking beta blockers

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. Severe Skin reactions: Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. Ischaemic colitis: 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. There have been rare cases of posterior reversible encephalopathy syndrome (PRES) / reversible cerebral vasoconstriction syndrome (RCVS) reported with sympathomimetic drugs, including pseudoephedrine

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 may occur 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: 8th SEP 2021

Sudafed Blocked Nose & Sinus 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 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, methyl dopa), tricyclic antidepressants, digoxin and cardiac glycosides, ergot alkaloids, warfarin and other coumarins, vasodilators and drugs which induce hepatic microsomal enzymes. Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risk factors. See SPC for further details.

Pregnancy and lactation: 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, 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: £4.39

Legal category: GSL.

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

PL Number: 12063/0067.

Date of preparation: 27/04/2023

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 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, methyl dopa), tricyclic antidepressants, digoxin and cardiac glycosides, ergot alkaloids, warfarin and other coumarins, vasodilators and drugs which induce hepatic microsomal enzymes. Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risk factors. See SPC for further details.

Pregnancy and lactation: 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, 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: £4.39

Legal category: GSL.

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

PL Number: 12063/0067.

Date of preparation: 27/04/2023

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. 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:

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, active or history of recurrent peptic ulcer/haemorrhage, cerebrovascular or other bleeding, unexplained 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 or presence of risk factors for stroke, risk of closed angle glaucoma, risk of urinary retention,

history of seizures, history of myocardial infarction, systemic lupus erythematosus, concomitant use of other vasoconstrictor agents and methylphenidate, concomitant use of MAOIs or use of MAOIs within the last two weeks.

Precautions:

Concomitant use with NSAIDs including COX-2 selective inhibitors, combination with medicines that can lower the epileptogenic threshold, not to be taken in cases of asthma unless advised by a doctor. Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur. 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. 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 gastrointestinal 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.

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. **Ischaemic colitis:** Some cases of ischaemic colitis have been reported with pseudoephedrine. Pseudoephedrine should be discontinued, and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop. **Ischaemic optic neuropathy:** Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs. This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say "sodium free". 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. erythema multiforme, Acute Generalised Exanthematous Pustulosis (AGEP). Serious skin reactions, some of them fatal, including exfoliative dermatitis, erythema multiforme, Acute Generalised Exanthematous Pustulosis (AGEP) Stevens-Johnson syndrome, Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS), and toxic epidermal necrolysis, have been reported very rarely in association with the use of NSAIDs. There have been rare cases of posterior reversible encephalopathy syndrome (PRES) / reversible cerebral vasoconstriction syndrome (RCVS) reported with sympathomimetic drugs, including pseudoephedrine. Symptoms reported include sudden onset of severe headache, nausea, vomiting, and visual disturbances. Most cases improved or resolved within a few days following appropriate treatment. Pseudoephedrine should be discontinued, and medical advice sought immediately if signs or symptoms of PRES/RCVS develop. **Masking of symptoms of underlying infections:** 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. Renal tubular acidosis and hypokalaemia may occur following acute overdose and in patients taking ibuprofen products over long periods at high doses (typically greater than 4 weeks), including doses exceeding the recommended daily dose. **For further info please refer to the SPC.**

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 further info in SPC.

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, 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, haemorrhagic stroke, ischemic stroke, convulsion, headache, Posterior Reversible Encephalopathy Syndrome, Reversible Cerebral Vasoconstriction Syndrome 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, Ischaemic optic neuropathy, acute generalized exanthematous pustulosis (AGEP), Photosensitivity reactions, Kounis syndrome.

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: 07 January 2024

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. 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, methyl dopa), tricyclic antidepressants, digoxin and cardiac glycosides, ergot alkaloids, warfarin and other coumarins, vasodilators and drugs which induce hepatic microsomal enzymes.

Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risk factors. See SPC for further details.

Pregnancy and Lactation: 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. See SPC for details.

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 preparation: 27/04/2023

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:

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. 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. Avoid in patients with prostatic enlargement.

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. Urinary retention has been reported (unknown frequency). This is most likely to occur in men with an enlarged prostate.

Price (ex-VAT): 16s: £4.64

Legal category: GSL.

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

PL Number: 12063/0112.

Date of preparation: 13 October 2022

Sudafed Congestion & Headache relief Day & Night Capsules (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 aged 16 years and over: 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. Children under 16 years: Not to be used unless recommended by a doctor. **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 – Caffeine. 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. 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. 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. This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'. **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. Phenylephrine may elevate blood pressure with headache, vomiting and rarely palpitations; tachycardia or reflex bradycardia; tingling and coolness of the skin. Nausea and insomnia have been noted. Rare reports of allergic reactions. Very rare cases of serious skin reactions have been reported. Urinary retention has been reported (unknown frequency). This is most likely to occur in men with an enlarged prostate.

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: 03/01/2023

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 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. Patients with long QT syndrome. Prolonged treatment may lead to reactive hyperemia 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.

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 Product Information

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

Reporting of side-effects: You can report side-effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard

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

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