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 30 mg per 5 ml 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: 10 ml every 4 to 6 hours, up to 4 times a day.
Children 6 to 12 years: 5 ml every 4 to 6 hours, up to 4 times a day. Not to be used for more than five days without the advice of a doctor.
Contraindications:
This product is contraindicated in children under the age of 6 years. It is also 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. This product contains 3.5 g of sucrose per 5 ml; therefore, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this

medicine. It also contains methyl hydroxybenzoate (E 218) and Ponceau 4R (E 124), both of which may cause allergic reactions.

Precautions:

Caution should be exercised when using the product in the presence of severe hepatic impairment or moderate renal impairment, and in occlusive vascular disease. Patients with difficulty in urination, urinary retention and/or prostatic hyperplasia, patients with thyroid disease who are receiving thyroid hormones are advised to consult a physician before using this product. 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. 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.

This product contains the following excipients:

- 3.5 g of sucrose per 5 ml, which should be taken into account in patients with diabetes mellitus.
- 3.73 mg of propylene glycol in each 5 ml.
- 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. There are no adequate and well-controlled studies of pseudoephedrine use in pregnant women. Pseudoephedrine is excreted in breast milk in small amounts, but the effect of this on breast-fed infants is not known.

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): 100 ml, £3.99
Legal category: P
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way High Wycombe, Buckinghamshire, HP12 4EG.
PL Number(s): PL 15513/0023
Date of prep: 18 MAY 2025

Sudafed Decongestant Tablets (pseudoephedrine hydrochloride) Product Information

Presentation:
Reddish-brown, round, biconvex film-coated tablets, with 'Sudafed' on one side. Tablets contain pseudoephedrine hydrochloride 60 mg.
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 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. There are no adequate and well-controlled studies in pregnant women. Pseudoephedrine is excreted in breast milk in small amounts, but the effect of this on breast-fed infants is not known.

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): 12's £4.17
Legal category: P
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way High Wycombe, Buckinghamshire, HP12 4EG.
PL Number(s): PL 15513/0024
Date of prep: 18 MAY 2025

Sudafed Blocked Nose & Sinus Capsules (paracetamol, caffeine, phenylephrine hydrochloride) Product Information

Presentation:

Red/blue capsules containing paracetamol 500 mg, caffeine 25 mg, phenylephrine hydrochloride 6.1 mg.

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: two capsules every 4 to 6 hours, as required, up to a maximum of 4 doses in 24 hours. Do not take more than 8 capsules (or 4 doses) in 24 hours. Dosage should not be continued for longer than 3 days without consulting a doctor.

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

Precautions:
Sudafed Blocked Nose & Sinus Capsules contains paracetamol; it should not be taken with anything else containing paracetamol. Paracetamol-containing drugs should be given with caution to patients with severe renal or severe hepatic impairment, Raynaud's Phenomenon, and diabetes mellitus. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring, is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors. Paracetamol has known interactions with domperidone, metoclopramide, and cholestyramine. Please seek medical advice before taking paracetamol-caffeine-phenylephrine in combination with the following drugs: warfarin and other coumarins, drugs that induce hepatic microsomal enzymes (e.g., alcohol, barbiturates, MAOIs, tricyclic antidepressants, amitriptyline), flucloxacillin, sympathomimetics amines, vasodilators, beta-blockers, other hypertensives (including debrisoquine, guanethidine, reserpine, methyldopa), digoxin and cardiac glycosides, ergot alkaloids. This medicine contains less than 1 mmol sodium (23 mg) per 2 capsules, that is to say, it is essentially 'sodium-free'.

Pregnancy and Lactation:
A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency. Paracetamol is excreted in breast milk in low concentrations; however, available published data do not contraindicate breastfeeding. The half-life of caffeine during pregnancy is prolonged and may contribute to hyperemesis gravidarum (morning sickness). It also appears in breastmilk and irritability and poor sleeping pattern in the infant have been reported. Due to the vasoconstrictive properties of phenylephrine, this medicine should be used with caution in patients with a history of

pre-eclampsia. Phenylephrine may also reduce placental perfusion. There is no information on use of phenylephrine in lactation.
Side effects:
Common (phenylephrine): nervousness, headache, dizziness, insomnia, increased blood pressure, nausea, vomiting, diarrhoea.
Rare or very rare (paracetamol): thrombocytopenia, agranulocytosis, anaphylaxis, cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson syndrome, toxic epidermal necrolysis, bronchospasm, hepatic dysfunction.
Not known (paracetamol): high anion gap metabolic acidosis.
Not known (caffeine): nervousness, anxiety, irritability, restlessness, excitability, dizziness.
Not known (phenylephrine): mydriasis, acute angle closure glaucoma (most likely to occur in those with closed angle glaucoma), tachycardia, palpitations, allergic reactions (e.g. rash, urticaria, allergic dermatitis), hypersensitivity reactions (including cross-sensitivity with other sympathomimetics), dysuria, urinary retention.
Please refer to Summary of Product Characteristics for detailed information.
RRP (ex-VAT): 16's £4.58
Legal category: GSL.
PL Holder: Wrafton Laboratories Ltd, Wrafton, Braunton, Devon. EX33 2DL.
PL Number(s): PL 12063/0067
Date of prep: 25 APR 2025

Sudafed Congestion & Headache Max Strength Capsules (paracetamol, caffeine, phenylephrine hydrochloride) Product Information

Presentation:
Red/blue capsules containing paracetamol 500 mg, caffeine 25 mg, phenylephrine hydrochloride 6.1 mg.
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: two capsules every 4 to 6 hours, as required, up to a maximum of 4 doses in 24 hours. Do not take more than 8 capsules (or 4 doses) in 24 hours. Dosage should not be continued for longer than 3 days without consulting a doctor.
Contraindications:
This product is contraindicated for use in children under 16 years of age, in individuals with known hypersensitivity to paracetamol, caffeine, phenylephrine, or to any of the product constituents. Sudafed Congestion & Headache Max Strength Capsules, hard contains caffeine and should be given with care to patients with a history of peptic ulcer. This product also contains phenylephrine, which is contraindicated in patients with severe coronary heart disease and cardiovascular disorders, hypertension, and hyperthyroidism. This product should also not be used by individuals who are either currently taking, or who have taken monoamine oxidase inhibitors (MAOIs) within the preceding 14 days.
Precautions:

Sudafed Congestion & Headache Max Strength Capsules contains paracetamol; it should not be taken with anything else containing paracetamol. Paracetamol-containing drugs should be given with caution to patients with severe renal or severe hepatic impairment, Raynaud's Phenomenon, and diabetes mellitus. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring, is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors. Paracetamol has known interactions with domperidone, metoclopramide, and cholestyramine. Please seek medical advice before taking paracetamol-caffeine-phenylephrine in combination with the following drugs: warfarin and other coumarins, drugs that induce hepatic microsomal enzymes (e.g., alcohol, barbiturates, MAOIs, tricyclic antidepressants, amitriptyline), flucloxacillin, sympathomimetics amines, vasodilators, beta-blockers, other hypertensives (including debrisoquine, guanethidine, reserpine, methyldopa), digoxin and cardiac glycosides, ergot alkaloids. This medicine contains less than 1 mmol sodium (23 mg) per 2 capsules, that is to say, it is essentially 'sodium-free'.

Pregnancy and Lactation:

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency. Paracetamol is excreted in breast milk in low concentrations; however, available published data do not contraindicate breastfeeding. The half-life of caffeine during pregnancy is prolonged and may contribute to hyperemesis gravidarum (morning sickness). It also appears in breastmilk and irritability and poor sleeping pattern in the infant have been reported. Due to the vasoconstrictive properties of phenylephrine, this medicine should be used with caution in patients with a history of pre-eclampsia. Phenylephrine may also reduce placental perfusion. There is no information on use of phenylephrine in lactation.

Side effects:

Common (phenylephrine): nervousness, headache, dizziness, insomnia, increased blood pressure, nausea, vomiting, diarrhoea.

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

Not known (paracetamol): high anion gap metabolic acidosis.

Not known (caffeine): nervousness, anxiety, irritability, restlessness, excitability, dizziness.

Not known (phenylephrine): mydriasis, acute angle closure glaucoma (most likely to occur in those with closed angle glaucoma), tachycardia, palpitations, allergic reactions (e.g. rash, urticaria, allergic dermatitis), hypersensitivity reactions (including cross-sensitivity with other sympathomimetics), dysuria, urinary retention.

Please refer to Summary of Product Characteristics for detailed information.

RRP (ex-VAT): 16's £4.58
Legal category: GSL.
PL Holder: Wrafton Laboratories Ltd, Wrafton, Braunton, Devon. EX33 2DL.
PL Number(s): PL 12063/0067
Date of prep: 25 APR 2025

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

Presentation:
Yellow, round film-coated tablets containing pseudoephedrine hydrochloride 30 mg and ibuprofen 200 mg.
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, with a 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 1 mmol sodium (23 mg) 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.
RRP (ex VAT): 12's £4.71; 24's £7.24
Legal category: P
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way High Wycombe, Buckinghamshire, HP12 4EG
PL Number(s): PL 15513/0396
Date of prep: 20 Feb 2025

Sudafed Sinus Max Strength Capsules Hard (paracetamol, caffeine, phenylephrine hydrochloride) Product Information

Presentation:
Red/blue capsules containing paracetamol 500 mg, caffeine 25 mg, phenylephrine hydrochloride 6.1 mg.
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: two capsules every 4 to 6 hours, as required, up to a maximum of 4 doses in 24 hours. Do not take more than 8 capsules (or 4 doses)

in 24 hours. Dosage should not be continued for longer than 3 days without consulting a doctor.

Contraindications:

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

Precautions:

Sudafed Sinus Max Strength Capsules, Hard contains paracetamol; it should not be taken with anything else containing paracetamol. Paracetamol-containing drugs should be given with caution to patients with severe renal or severe hepatic impairment, Raynaud's Phenomenon, and diabetes mellitus. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition or other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring, is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors. Paracetamol has known interactions with domperidone, metoclopramide, and cholestyramine. Please seek medical advice before taking paracetamol-caffeine-phenylephrine in combination with the following drugs: warfarin and other coumarins, drugs that induce hepatic microsomal enzymes (e.g., alcohol, barbiturates, MAOIs, tricyclic antidepressants, amitriptyline), flucloxacillin, sympathomimetics amines, vasodilators, beta-blockers, other hypertensives (including debrisoquine, guanethidine, reserpine, methyldopa), digoxin and cardiac glycosides, ergot alkaloids. This medicine contains less than 1 mmol sodium (23 mg) per 2 capsules, that is to say, it is essentially 'sodium-free'.

Pregnancy and Lactation:

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency. Paracetamol is excreted in breast milk in low concentrations; however, available published data do not contraindicate breastfeeding. The half-life of caffeine during pregnancy is prolonged and may contribute to hyperemesis gravidarum (morning sickness). It also appears in breastmilk and irritability and poor sleeping pattern in the infant have been reported. Due to the vasoconstrictive properties of phenylephrine, this medicine should be used with caution in patients with a history of pre-eclampsia. Phenylephrine may also reduce placental perfusion. There is no information on use of phenylephrine in lactation.

Side effects:

Common (phenylephrine): nervousness, headache, dizziness, insomnia, increased blood pressure, nausea, vomiting, diarrhoea.
Rare or very rare (paracetamol): thrombocytopenia, agranulocytosis, anaphylaxis, cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson syndrome, toxic epidermal necrolysis, bronchospasm, hepatic dysfunction.
Not known (paracetamol): high anion gap metabolic acidosis.
Not known (caffeine): nervousness, anxiety, irritability, restlessness, excitability, dizziness.
Not known (phenylephrine): mydriasis, acute angle closure glaucoma (most likely to occur in those with closed angle glaucoma), tachycardia, palpitations, allergic reactions (e.g. rash, urticaria, allergic dermatitis), hypersensitivity reactions (including cross-sensitivity with other sympathomimetics), dysuria, urinary retention.
Please refer to Summary of Product Characteristics for detailed information.
RRP (ex VAT): 16's £4.58
Legal category: GSL
PL Holder: Wrafton Laboratories Ltd, Wrafton, Braunton, Devon. EX33 2DL.
PL Number(s): PL 12063/0067
Date of prep: 25 APR 2025

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:
White, capsule-shaped, film-coated tablet embossed with "PGP", free from specks and blemishes, and 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:
Sudafed Mucus Relief Triple Action Cold & Flu Tablets or Benylin Mucus Cough & Cold All in One Relief Tablets is not recommended for use in children under 12 years of age. Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic

acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. 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:

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

Side effects:

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

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

Not known: high anion gap metabolic acidosis, allergic reactions, angioedema, anaphylactic reactions, dyspnoea, nausea, vomiting, abdominal discomfort, rash, urticaria, mydriasis, acute angle closure glaucoma (most likely to occur in those with closed angle glaucoma), tachycardia, palpitations, allergic reactions (e.g. rash, urticaria, allergic dermatitis), hypersensitivity reactions (including cross-sensitivity with other sympathomimetics), dysuria, urinary retention.

Please refer to Summary of Product Characteristics for detailed information.

RRP (ex-VAT): *Sudafed Mucus Relief Triple Action Cold & Flu Tablets 16's:* £4.83; *Benylin Mucus Cough & Cold All in One Relief Tablets 16's* £4.66

Legal category: GSL.

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

PL Number(s): PL 12063/0112

Date of prep: 24 MAR 2025

Sudafed Congestion & Headache Relief Day & Night Capsules (paracetamol, caffeine, phenylephrine hydrochloride) Product Information

Presentation:
Red/yellow day capsules containing paracetamol 500 mg, caffeine 25 mg, phenylephrine hydrochloride 6.1 mg; dark blue/light blue night capsules containing paracetamol 500 mg, phenylephrine hydrochloride 6.1 mg.
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:
This product is contraindicated in patients with severe renal impairment. Paracetamol should be used with caution.
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, tricyclic antidepressants 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. Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due

to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. Possible interactions with Sudafed Congestion & Headache relief Day & Night Capsules may occur with other paracetamol-containing products and other cold and flu medicines. Paracetamol has known interactions with domperidone, metoclopramide, and cholestyramine. Please seek medical advice before taking paracetamol-caffeine-phenylephrine in combination with the following drugs: warfarin and other coumarins, drugs that induce hepatic microsomal enzymes (e.g., alcohol, barbiturates, MAOIs, tricyclic antidepressants, amitriptyline), probenecid, chloramphenicol, flucloxacillin, sympathomimetics amines, vasodilators, beta-blockers, other hypertensives (including debrisoquine, guanethidine, reserpine, methyldopa), digoxin and cardiac glycosides, 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. Caffeine has an antagonistic effect towards the action of sedative and tranquilizers, and it may also enhance the tachycardia effect of some decongestants. 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 which causes congenital malformation when administered during pregnancy and has been shown to have possible associations with foetal hypoxia; this ingredient is contraindicated during pregnancy. There is no information on use of phenylephrine in lactation. A large amount of data on pregnant women indicates no malformative nor feto/neonatal toxicity of paracetamol. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. Paracetamol is excreted in breast milk in low concentrations; however, available published data do not contraindicate breastfeeding. The half-life of caffeine during pregnancy is prolonged and may contribute to hyperemesis gravidarum (morning sickness). It also appears in breastmilk and irritability and poor sleeping pattern in the infant have been reported.

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), serious skin reactions, toxic epidermal necrolysis (TEN), drug-induced dermatitis, Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), sterile pyuria.

Not known: high anion gap metabolic acidosis, 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): 16's (12 day/4 night) £4.83

Legal category: GSL.

PL Holder: Wrafton Laboratories Ltd, Wrafton, Braunton, Devon. EX33 2DL

PL number(s): PL 12063/0073

Date of prep: 17 APR 2025

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 to 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:
Uncommon: epistaxis.
Rare: nausea and headache.
Not known: burning sensation mucosal, nasal discomfort, nasal dryness, nasal pruritus, rhinalgia, sneezing, rebound congestion.
Please refer to Summary of Product Characteristics for detailed information.
RRP (ex VAT): £5.04
Legal category: GSL
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way High Wycombe, Buckinghamshire, HP12 4EG
PL Number(s): PL 15513/0074
Date of prep: 22 DEC 2022

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

Presentation:
Spray pump bottle containing 10 ml 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.

Contraindications:

Sudafed Plus Blocked Nose Spray is contraindicated in children under 12 years of age, in individuals with hypersensitivity to the active substances or to any of the excipients listed, with cardiovascular disease including hypertension, phaeochromocytoma, diabetes mellitus, hyperthyroidism, closed angle glaucoma with inflammation of the skin and/or mucosa of the nasal vestibule, dry inflammation of the nasal mucosa (rhinitis sicca). This product should not be used concomitantly with other sympathomimetic decongestants and beta blockers. It should also not be used by individuals who are either currently taking, or who have taken monoamine oxidase inhibitors (MAOIs) within the preceding 14 days. Individuals with a history of transsphenoidal hypophysectomy or other surgical interventions which expose the dura mater, should not use this product.

Precautions:

Sudafed Plus Blocked Nose Spray should be used 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, porphyria, and prostate hyperplasia. Use with caution in occlusive vascular disease. 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. This medicine is intended for short term use only. Prolonged treatment may lead to reactive hyperaemia of the nasal mucosa. This rebound effect may lead to nasal congestion or nasal obstruction during continued use or after discontinuation, resulting in repeated or even continuous use of the medicine by the patient. In case of misuse or use of excessive amounts of the spray, the absorption of xylometazoline can cause systemic adverse effects. Discontinue use of Sudafed Plus Blocked Nose Spray if any of the following occur: hallucinations, restlessness, sleep disturbances. Keep away from the eyes.

Concomitant use with antihypertensive agents (e.g. methyldopa) should be avoided due to the potential effect of Xylometazoline to increase blood pressure.

Concomitant use with medicines which potentially increase blood pressure (e.g. doxapram, ergotamin, oxytocin, or tricyclic antidepressants) should be avoided as the vasopressor effect may be increased. Concomitant use with sympathomimetics (e.g. pseudoephedrine, ephedrine, phenylephrine, oxymetazoline, xylometazoline, tramazoline, naphazoline) can lead to additive effects on the cardiovascular system and central nervous system. MAOIs such as moclobemide, and/or (Reversible Inhibitors of Monoamine Oxidase A (RIMAs) should not be given to patients treated with MAOIs or within 14 days of stopping treatment: increased risk of hypertensive crisis. Sudafed Plus Blocked Nose Spray may block the hypotensive effects of antihypertensives (including adrenergic neurone blockers and beta-blockers). In

addition, concomitant use of this product can increase the risk of arrythmias with use of cardiac glycosides, the risk of ergotism with the use of ergot alkaloids (ergotamine and methysergide), and the risk of hypertension with the use of appetite suppressants and amphetamine-like psychostimulants. There is no known interaction between dexpanthenol and other medicinal products.

Pregnancy and Lactation:

This medicine should not be used during pregnancy, as there is not sufficient data available concerning the use of xylometazoline hydrochloride by pregnant women. It should also not be used during the lactation period since it is not known whether xylometazoline hydrochloride is excreted in the breast milk.

Side effects:

Uncommon: hypersensitivity reaction (angioedema, skin rash, pruritus),
Rare: palpitations, tachycardia, hypertension.
Very rare: restlessness, insomnia, hallucinations, paranoid delusions, fatigue (drowsiness, sedation), headache, convulsions, arrhythmias, rebound congestion (rhinitis medicamentosa), nosebleed
Not known: irritability, anxiety, excitability, sneezing, burning, irritation, dryness of the nasal mucosa, nausea, tolerance with diminished effect.
Please refer to Summary of Product Characteristics for detailed information.

RRP (ex VAT): £6.25
Legal category: GSL
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way High Wycombe, Buckinghamshire, HP12 4EG
PL Number(s): PL 15513/0407
Date of prep: 06 MAY 2025