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 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, 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. 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. 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. 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. This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say, “sodium free”. **For further information 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 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.
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: 10 April 2024