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

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

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 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. This medicine contains less than 1mmol sodium (23mg) per tablet, i.e. essentially 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.

***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. **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, haemorhagic stroke, ischemic stroke,

convulsion, headache, palpitations, tachycardia, chest pain, arrhythmia, hypertension, thirst, vomiting, drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), urticaria, severe skin reaction including acute generalized exanthematous pustulosis (AGEP), hyperhidrosis, difficulty in micturition, euphoric mood, nervousness, somnolence, angioedema, urinary retention, dysuria, Ischaemic optic neuropathy, acute generalized exanthematous pustulosis (AGEP), Photosensitivity reactions

See SPC for further information

RRP (ex VAT): 12s, £4.04; 24s, £6.23

Legal category: P

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