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 hydrochloride and ibuprofen) Product Information

Presentation:
Yellow, round film-coated tablets containing pseudoephedrine hydrochloride 30mg and ibuprofen 200mg.

Uses:
Symptomatic treatment of nasal congestion associated with acute rhinosinusitis suspected to be of viral origin with headache and/or fever.
Dosage:
Adults and children over 15 years: 1 or 2 tablets every 6 hours, maximum 6 tablets per 24 hours. The maximum duration of treatment is 4 days for adults and 3 days for adolescents aged 15 years and older. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.
Contraindications:
This product is contraindicated in children under 15 years, in individuals with known hypersensitivity to ibuprofen, phenylephrine, acetylsalicylic acid, other NSAIDs, or to any of the product's excipients; in pregnant women during the third trimester of pregnancy and breast-feeding mothers; in individuals with a history of NSAID-related gastrointestinal bleeding or perforation, active or history of recurrent peptic ulcer/haemorrhage; cerebrovascular or other bleeding, unexplained haematopoietic abnormalities; severe hepatic impairment, severe acute or chronic kidney disease / renal failure, severe heart failure (NYHA Class IV); severe cardiovascular disorders, a history of myocardial infarction, coronary heart disease (heart disease, hypertension, angina pectoris), tachycardia; a history of stroke or presence of risk factors for stroke; hyperthyroidism, diabetes mellitus, phaeochromocytoma, closed-angle glaucoma, risk of urinary retention related to urethroprostatic disorders; history of seizures; systemic lupus erythematosus. This product should also not be used by individuals who are concomitantly taking oral or intranasal vasoconstrictor agents (e.g., nasal decongestants such as phenylpropanolamine, phenylephrine and ephedrine), methylphenidate, as well as by individuals who are taking, or who have taken monoamine oxidase inhibitors (MAOIs) within the preceding 14 days.
Precautions:
Concomitant use of Sudafed Sinus Pressure & Pain 200mg/30mg film-coated tablets with NSAIDs including COX-2 selective inhibitors, and in combination with medicines that can lower the epileptogenic threshold, should not be taken in cases of asthma unless advised by a doctor. If signs and symptoms such as fever (pyrexia),

erythema, or many small pustules are observed, administration of this medicine should be discontinued, and appropriate measures taken if needed. Psychosis, concomitant administration of antimigraine agents, hypertension, systemic lupus erythematosus and mixed connective tissue disease, neurological symptoms, patients with urethroprostatic disorders, blood clotting disorder, risk of gastro-intestinal bleeding, ulceration or perforation, history of gastrointestinal toxicity, caution with oral corticosteroids, anticoagulants, SSRIs or antiplatelet agents, history of gastrointestinal disease, heart failure, patients with chronically impaired renal or hepatic function, patients taking diuretics, patients who are hypovolaemic and the elderly, history of asthma, chronic headache. Patients should consult a doctor if symptoms worsen. Recommended dose and/or duration of treatment should not be exceeded since increased doses may result in toxicity. Continuous use can lead to tolerance resulting in an increased risk of overdosing. Depression may follow rapid withdrawal. Overdosage may result in nausea and vomiting. Some cases of ischaemic colitis have been reported with pseudoephedrine. This product should be discontinued, and medical advice sought if sudden abdominal pain, rectal bleeding, or other symptoms of ischaemic colitis develop. Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. This product should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs. Ibuprofen may cause a severe allergic reaction, especially in patients allergic to acetylsalicylic acid. Symptoms may include hives, facial swelling, asthma (wheezing), shock, skin reddening, rash or blisters with or without pyrexia or erythema. Severe cutaneous adverse reactions (SCARs) including exfoliative dermatitis, erythema multiforme, Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS syndrome), and acute generalized exanthematous pustulosis (AGEP), which can be life-threatening or fatal, have been reported in association with the use of ibuprofen. Kounis syndrome, defined as cardiovascular symptoms secondary to an allergic or hypersensitive reaction associated with constriction of coronary arteries, has been reported in patients treated with Sudafed Sinus Pressure & Pain 200mg/30mg film-coated tablets; this can potentially lead to myocardial infarction. Prolonged use of ibuprofen-containing products at higher than recommended doses or overdose may result in renal tubular acidosis and hypokalaemia. Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported with the use of pseudoephedrine-containing products. The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure. Pseudoephedrine should be discontinued, and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances. This medicine can mask symptoms of infection, which may lead to delayed initiation of appropriate treatment and thereby worsening the outcome of the infection. This has been observed in bacterial community acquired pneumonia and bacterial complications to varicella. When this medicine is administered for fever or pain relief in relation to infection, monitoring of infection is advised. In non-hospitals settings, the patient should consult a doctor if symptoms persist or worsen. This medicine contains less than 1mmol sodium (23mg) per tablet, that is to say, “sodium free”.

Pregnancy and Lactation:

Pregnancy: Contraindicated during the third trimester. Given only if necessary and under supervision of physician during first and second trimester. *Lactation:* Contraindicated during lactation.

Please refer to Summary of Product Characteristics for detailed 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
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