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

## **Sudafed Sinus Pain Relief 200mg/6.1mg Tablets (Ibuprofen 200 mg, Phenylephrine hydrochloride 6.1 mg) Product Information**

### **Presentation:**

Green, round bi-convex sugar coated tablet.

### **Uses:**

For the relief of symptoms of cold and flu with associated congestion, including aches and pains, headache, fever, sore throat, blocked nose and sinuses.

### **Dosage:**

*Adults, the elderly and children between 12 and 18 years:* Two tablets every 8 hours, with or after food. Leave at least 4 hours between doses and do not exceed six tablets in any 24 hour period. A doctor should be consulted if the symptoms worsen or if the product is required for longer than 3 days in children between 12 and 18 years, or after 10 days in adults.

### **Contraindications:**

Hypersensitivity to ibuprofen, aspirin, and other NSAIDs, phenylephrine hydrochloride or any of the excipients in the product. Hypertension and severe coronary heart disease. Active or history of recurrent peptic ulcer/haemorrhage. History of NSAID related gastrointestinal bleeding or perforation. Severe heart failure, renal failure or hepatic failure. Use with concomitant NSAIDs including cyclo-oxygenase-2 specific inhibitors. Patients being treated with monoamine oxidase inhibitors or within 14 days of ceasing such treatment. Patients with diabetes mellitus. Patients with closed angle glaucoma. Patients with hyperthyroidism. Patients suffering from prostatic enlargement. Patients suffering with phaeochromocytoma. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.

### **Precautions:**

Use with caution in the elderly; women trying conceive; dehydrated children; history of GI disease or toxicity; concomitant medications increasing the risk of GI toxicity; hepatic or renal dysfunction; bronchial asthma or allergic disease; hypertension or heart failure; patients with increased risk factors for cardiovascular events; patients with occlusive vascular disease; SLE and mixed connective tissue disease. Should be used with caution in combination with: Anti-coagulants; Antihypertensives and diuretics; Corticosteroids; Anti-platelet agents and selective serotonin-reuptake inhibitors (SSRIs); Cardiac glycosides; Lithium; Methotrexate; Ciclosporin; Mifepristone; Tacrolimus; Zidovudine; Quinolone antibiotics; Sympathomimetic Amines; Beta-blockers and other Vasodilators; Anticholinergic Drugs; Cardiac

Glycosides. Acute generalised exanthematous pustulosis (AGEP) has been reported in relation to ibuprofen containing products.

**Pregnancy and Lactation:**

Not recommended.

**Side effects:**

Uncommon: Hypersensitivity reactions with urticaria and pruritus; headache; tachycardia; cardiac arrhythmias; palpitations; hypertension; abdominal pain; nausea; dyspepsia; dizziness and tinnitus.

Rare: Diarrhoea; flatulence; constipation; vomiting; non-specific allergic reactions.

Very rare: Urinary retention in males; acute renal failure; papillary necrosis; severe forms of skin reactions such as bullous reactions; including Stevens Johnson syndrome; erythema multiforme and toxic epidermal necrolysis can occur; liver disorders; peptic ulcer; perforation or gastrointestinal haemorrhage; melaena; haematemesis; ulcerative stomatitis; gastritis; exacerbation of ulcerative colitis and Crohn's disease; aseptic meningitis (single cases); severe hypersensitivity reactions (anaphylaxis, angioedema or severe shock); haematopoietic disorders (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis). acute generalised exanthematous pustulosis (AGEP).

Not known: Drug reaction with eosinophilia and systemic symptoms (DRESS syndrome)

**RRP (ex VAT):** £4.58

**Legal category:** GSL

**PL Holder:** Galpharm Healthcare Limited, Wrafton, Braunton, Devon, EX33 2DL

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