

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 Max Strength Capsules Hard (Paracetamol 500mg, Caffeine 25mg, Phenylephrine 6.1mg) Product Information

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

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:* 2 caps every 4-6 hours to a max of 4 doses in any 24 hours. Do not exceed 8 caps in any 24 hours. Dosage should not be continued for longer than 3 days without consulting a doctor.

Contraindications: Use in children under 16 years; hypersensitivity, severe coronary heart disease and cardiovascular disorders, history of peptic ulcer, hypertension, hyperthyroidism, use with or within two weeks of receiving MAOIs. Avoid in patients with prostatic enlargement.

Precautions: Severe renal or severe hepatic impairment, Raynaud's Phenomenon, diabetes mellitus. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. Should not be taken concomitantly with other paracetamol containing medicines. Possible interactions: metoclopramide, domperidone, cholestyramine, monoamine oxidase inhibitors (including moclobemide), sympathomimetic amines, beta-blockers and other antihypertensives (including debrisoquine, guanethidine, reserpine, methyldopa), tricyclic antidepressants, digoxin and cardiac glycosides, ergot alkaloids, warfarin and other coumarins, vasodilators and drugs which induce hepatic microsomal enzymes. See SPC for further details.

Pregnancy and Lactation: The product should be used in pregnancy only if the benefits outweigh this risk. Consult doctor before use.

Side effects: Thrombocytopenia, agranulocytosis, anaphylaxis, cutaneous hypersensitivity reactions including skin rashes, angioedema and Stevens Johnson syndrome, cross-sensitivity with other sympathomimetics, toxic epidermal necrolysis, bronchospasm and hepatic dysfunction, nervousness, anxiety, irritability, restlessness, excitability, dizziness, headache, insomnia, increased blood pressure, nausea, vomiting, diarrhoea, 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), dysuria, urinary retention. See SPC for details.

RRP (ex VAT): 16s, £3.90

Legal category: GSL

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

PL Number: PL 12063/0067

Date of prep: 29/08/2019