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

Adverse events should also be reported to McNeil Products Limited on freephone 0808 238 9999.

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. This medicine contains less than 1 mmol sodium (23 mg) per 2 capsules, that is to say essentially 'sodium-free'. 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.
Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risk factors. See SPC for further details.
Pregnancy and Lactation: The product should be used in pregnancy only if the benefits outweigh this risk; moreover, it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency. Consult doctor before use.
Side effects: Thrombocytopenia, agranulocytosis, anaphylaxis, cutaneous hypersensitivity reactions including skin rashes, angiodema 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, £4.39

Legal category: GSL
PL Holder: Wrafton Laboratories Ltd, Wrafton, North Devon. EX33 2DL.
PL Number: PL 12063/0067
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