

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 Mucus Relief Day & Night Capsules or Sudafed Congestion & Headache relief Day & Night Capsules (Product Information)

Presentation: Red/yellow day capsules containing paracetamol 500mg, caffeine 25mg, phenylephrine 6.1mg; dark blue/light blue night capsules containing paracetamol 500mg, phenylephrine 6.1mg

Uses: Symptomatic relief of common cold and influenza, including aches and pains, sore throat, headache, fatigue and drowsiness (day capsule only), nasal congestion and fever

Dosage: Adults and children aged 16 years and over: 2 red/yellow caps every 4-6 hours during the day as required, followed by 2 dark blue/ light blue caps at bedtime. Leave at least 4-6 hours between doses. Do not take more than 8 caps in 24 hours. Children under 16 years: Not to be used unless recommended by a doctor.

Contraindications: Hypersensitivity to the active ingredients or excipients, severe coronary heart disease and cardiovascular disorders, hypertension, hyperthyroidism, patients currently receiving or within 2 weeks of stopping therapy with MAOIs. History of peptic ulcer (day capsules only – Caffeine. 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. Keep out of the reach and sight of children. Possible interactions: metoclopramide, domperidone, colestyramine, anticoagulants, other sympathomimetics, vasodilators, beta-blockers, drugs which induce hepatic microsomal enzymes. This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'. **See SPC for further details.**

Pregnancy and lactation: Consult doctor before use.

Side-effects: Nausea and insomnia (day capsules only). Adverse effects of paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol. Phenylephrine may elevate blood pressure with headache, vomiting and rarely palpitations; tachycardia or reflex bradycardia; tingling and coolness of the skin. Nausea and insomnia have been noted. Rare reports of allergic reactions. Very rare cases of serious skin reactions have been reported. Urinary retention has been reported (unknown frequency). This is most likely to occur in men with an enlarged prostate.

RRP (ex-VAT): 16s (12 day/4 night): £4.00

Legal category: GSL.

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

PL numbers: 12063/0073

Date of preparation: 21/07/2021

REF-PI-BE-0073