

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.

Benylin Cold & Flu Max Strength Capsules (Paracetamol, Phenylephrine hydrochloride, Caffeine) Product Information

Presentation: Red/yellow capsule containing 500 mg Paracetamol, and 6.1 mg Phenylephrine HCl and 25 mg Caffeine.

Uses: For the relief of symptoms associated with the common cold and influenza, including relief of aches and pains, sore throat, headaches, fatigue and drowsiness, nasal congestion and lowering of temperature.

Dosage:

Adults, the elderly and children aged 16 years and over: 2 capsules every 4 hours, up to a maximum of 8 capsules in 24 hours. Leave 4-6 hours between doses. Patients should not use for longer than 3 days without consulting a doctor.

Contraindications:

Use in children under 16 years; Hypersensitivity to paracetamol or any of the other constituents. Caffeine: Should be given with care to patients with a history of peptic ulcer, Phenylephrine Hydrochloride: severe coronary heart disease and cardiovascular disorders, hypertension, hyperthyroidism, history of peptic ulcer. Within two weeks of taking or stopping MAOIs. Avoid in patients with prostatic enlargement.

Precautions:

Caution in severe renal or severe hepatic impairment, Raynaud's phenomenon and diabetes mellitus. Should not be taken alongside other paracetamol containing products. 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. See SPC for further details.

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

Side effects:

Paracetamol: 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. Very rare cases of serious skin reactions have been reported.

Caffeine: Nausea and insomnia have been noted.

Phenylephrine hydrochloride: may elevate blood pressure with headache, vomiting and rarely palpitations; tachycardia or reflex bradycardia; tingling and coolness of the skin. There have been rare reports of allergic reactions. Urinary retention has been reported (unknown frequency). This is most likely to occur in men with an enlarged prostate.

RRP (ex-VAT): 16 capsules £3.90.

Legal category: GSL.

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

PL Number: 12063/0066.

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