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 0808 238 9999.

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 hydrochloride 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 to 6 hours between doses. Patients should not use for longer than 3 days without consulting a doctor.
Contraindications:
This product is contraindicated for use in children under 16 years of age, in individuals with known hypersensitivity to paracetamol, caffeine, phenylephrine, or to any of the product's excipients. Benylin Cold & Flu Max Strength Capsules, hard contains caffeine and should be given with care to patients with a history of peptic ulcer. This product also contains phenylephrine, which is contraindicated in patients with severe coronary heart disease and cardiovascular disorders, hypertension, hyperthyroidism. This product should not be used by individuals who are either currently taking, or who have taken monoamine oxidase inhibitors (MAOIs) within the preceding 14 days.
Precautions:
Taking more than the recommended dose of Benylin Cold & Flu Max Strength Capsules, hard may cause liver damage. Concurrent intake of this product with other paracetamol-containing medicines can also lead to overdose and should therefore be avoided. Caution is advised in the use of this product in patients with severe hepatic impairment, severe renal impairment, or chronic alcohol use. Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. Patients suffering from enlargement of the prostate gland, Raynaud's phenomenon, and diabetes mellitus should consult a physician before taking the product. This medicine contains less than 1 mmol sodium

(23 mg) per 2 capsules, that is to say essentially ‘sodium-free’. Paracetamol has known interactions with domperidone, metoclopramide, and cholestyramine. Please seek medical advice before taking paracetamol-caffeine-phenylephrine in combination with the following drugs: MAOIs (including moclobemide), sympathomimetics amines, vasodilators, beta-blockers, other hypertensives (including debrisoquine, guanethidine, reserpine, methyldopa), tricyclic antidepressants (e.g., amitriptyline), digoxin and cardiac glycosides, ergot alkaloids, warfarin and other coumarins, drugs that induce hepatic microsomal enzymes (e.g., alcohol, barbiturates, MAOIs, tricyclic antidepressants), and flucloxacillin.

Pregnancy and lactation:

Consult a doctor before use. This product should not be used in pregnancy unless benefits to the mother outweigh risk to foetus. No ill effects due to paracetamol use in human pregnancy using the recommended dosage have been shown; however, patients should follow the advice of their doctor regarding its use. Paracetamol is excreted in breast milk in low concentrations; however, available published data do not contraindicate breastfeeding. The half-life of caffeine during pregnancy is prolonged and may contribute to hyperemesis gravidarum (morning sickness). It also appears in breastmilk and irritability and poor sleeping pattern in the infant have been reported. Due to the vasoconstrictive properties of phenylephrine, this medicine should be used with caution in patients with a history of pre-eclampsia. Phenylephrine may also reduce placental perfusion. There is no information on use of phenylephrine in lactation.

Side effects:

Common: nervousness, headache, dizziness, insomnia, increased blood pressure, nausea, vomiting, diarrhoea.

Rare or very rare (paracetamol): thrombocytopenia, agranulocytosis, anaphylaxis, cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson syndrome, toxic epidermal necrolysis, bronchospasm, hepatic dysfunction, acute pancreatitis

Not known: high anion gap metabolic acidosis, nervousness, anxiety, irritability, restlessness, excitability, dizziness, 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), hypersensitivity reactions (including cross-sensitivity with other sympathomimetics), dysuria, urinary retention.

Please refer to Summary of Product Characteristics for detailed information

RRP (ex-VAT): 16 capsules, £4.41.

Legal category: GSL.

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

PL Number: 12063/0066.

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