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 freephone 0808 238 9999.

Sudafed Congestion & Headache relief Day & Night Capsules (Paracetamol, Caffeine, Phenylephrine Hydrochloride) Product Information

Presentation:
Red/yellow day capsules containing paracetamol 500mg, caffeine 25mg, phenylephrine hydrochloride 6.1mg; dark blue/light blue night capsules containing paracetamol 500mg, phenylephrine hydrochloride 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, elderly, and children aged 16 years and over: two red/yellow capsules every 4 to 6 hours during the day as required, followed by two dark blue/light blue capsules at bedtime. Leave at least 4 to 6 hours between doses. Do not take more than 8 capsules (or 4 doses) in 24 hours.
Children under 16 years: not recommended.
Frail and immobile elderly patients: reduced dose or frequency is recommended; please seek medical advice before use.

Contraindications:
This product is contraindicated in individuals with known hypersensitivity to paracetamol, caffeine, phenylephrine, or to any of the product's excipients; hypertension, cardiovascular disorders, severe hepatic impairment, severe renal impairment, hyperthyroidism, diabetes mellitus, phaeochromocytoma, angle closure glaucoma, and prostatic enlargement. This product should not be used by individuals who are concomitantly taking beta blockers or other sympathomimetics (such as decongestants, appetite suppressants, amphetamine-like psychostimulants), and in individuals who are taking, or who have taken monoamine oxidase inhibitors (MAOIs) within the preceding 14 days.

Precautions:
Sudafed Congestion & Headache relief Day & Night Capsules is not recommended for use in children under 16 years of age.
Paracetamol-containing drugs should be given with caution to patients diagnosed with the following conditions and are advised to seek medical advice before using this

product: renal impairment and mild or moderate hepatic impairment, chronic alcoholism, Gilbert's Syndrome (familial non-haemolytic jaundice), glucose-6-phosphate dehydrogenase deficiency, haemolytic anaemia, glutathione deficiency, malnutrition, dehydration, urinary retention, occlusive vascular disease (e.g., Raynaud's syndrome). Moreover, precaution should be observed in patients with asthma who are also sensitive to acetylsalicylic acid since mild bronchospasms have been reported in association with paracetamol (cross-reaction).
Hepatotoxicity at therapeutic doses of paracetamol has been reported, with a higher risk for hepatotoxicity observed in individuals weighing less than 50kg, renal and hepatic impairment, chronic alcoholism, acute and chronic malnutrition, and concomitant intake of hepatotoxic drugs. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.
Possible interactions with Sudafed Congestion & Headache relief Day & Night Capsules may occur with the following: other paracetamol-containing products, cold and flu medicines, floxacillin, metoclopramide, domperidone, cholestyramine, warfarin and other coumarins, alcohol, barbiturates, probenecid, other sympathomimetics, vasodilators, beta-blockers, digoxin and cardiac glycosides, and ergot alkaloids.
Excessive intake of caffeinated products such as coffee, tea, and some canned drinks, should be avoided while taking this product. Caution should be observed when this product is given to patients with a history of peptic ulcer.
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say, it is essentially 'sodium-free'.
Please refer to Summary of Product Characteristics for detailed information.
Pregnancy and lactation: This product contains phenylephrine; this ingredient is contraindicated during pregnancy.
Side-effects:
Rare: allergies (not including angioedema), allergic reactions, mydriasis, acute angle closure glaucoma, palpitations, tachycardia, reflex bradycardia, rash, urticaria, allergic dermatitis.
Very rare: blood dyscrasias (e.g., thrombocytopenia, leukopenia, pancytopenia, neutropenia, agranulocytosis), anaphylaxis, bronchospasms in patients sensitive to aspirin and other NSAIDs, hepatic dysfunction, cutaneous hypersensitivity reactions (e.g., skin rashes, pruritus, sweating, purpura, urticaria, angioedema), toxic epidermal necrolysis (TEN), drug-induced dermatitis, Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), sterile pyuria.
Not known: insomnia, nervousness, dizziness, nausea, headache, elevated blood pressure, cardiac arrhythmias, vomiting, diarrhoea, tingling and coolness of the skin, dysuria, urinary retention.
Please refer to Summary of Product Characteristics for detailed information.
RRP (ex-VAT): 16s (12 day/4 night): £4.64
Legal category: GSL.
PL holder: Wrafton Laboratories Ltd, Wrafton, Braunton, Devon. EX33 2DL
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