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 (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, elderly and children aged 16 years and over: 2 red/yellow capsules every 4-6 hours during the day as required, followed by 2 dark blue/ light blue capsules at bedtime. Leave at least 4-6 hours between doses. Do not take more than 8 capsules (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:
Hypersensitivity to the active ingredients or excipients, current or recent intake of monoamine oxidase inhibitors within the last two weeks, hypertension, cardiovascular disorders, severe hepatic impairment, severe renal impairment, hyperthyroidism, diabetes mellitus, pheochromocytoma, current treatment with tricyclic antidepressants or beta-blockers, angle closure glaucoma, current use of other sympathomimetics (such as decongestants, appetite suppressants, amphetamine-like psychostimulants).
Avoid in patients with prostatic enlargement.
Precautions:
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). 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: 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. In addition, 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: allergic reactions, rash, urticaria, allergic dermatitis, palpitations, tachycardia or reflex bradycardia, Mydriasis and acute angle closure glaucoma have also been reported; this is more likely to occur in those with individuals with closed angle glaucoma.

Very rare: thrombocytopenia, leukopenia, pancytopenia, neutropenia and agranulocytosis, anaphylaxis, bronchospasms, hepatic dysfunction, skin rashes, pruritus, sweating, purpura, angioedema, toxic epidermal necrolysis (TEN), drug-induced dermatitis, Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), sterile pyuria.

Not known: nausea, vomiting, diarrhoea, tingling and coolness of skin, elevated blood pressure, cardiac arrhythmias, headache, insomnia, nervousness, dizziness. Dysuria and urinary retention have also been reported; this is more likely to occur in men with an enlarged prostate.

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

PL numbers: 12063/0073

Date of preparation: 13/02/2024