Adverse events should be reported. Reporting forms and information can be found at www. https://yellowcard.mhra.gov.uk/

Adverse events should also be reported to McNeil Products Limited on freephone 0808 238 9999.

Sudafed Blocked Nose & Sinus Capsules (paracetamol, caffeine, phenylephrine hydrochloride) Product Information

Presentation:
Red/blue capsules containing paracetamol 500 mg, caffeine 25 mg, phenylephrine hydrochloride 6.1 mg.

Uses:
Symptomatic relief of the pain and congestion of sinusitis, including relief of aches and pains, headache, nasal congestion and lowering of temperature.

Dosage:
Adults and children over 16 years: two capsules every 4 to 6 hours, as required, up to a maximum of 4 doses in 24 hours. Do not take more than 8 capsules (or 4 doses) in 24 hours. Dosage should not be continued 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 constituents. Sudafed Blocked Nose & Sinus Capsules contain 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, and hyperthyroidism. This product should also not be used by individuals who are either currently taking, or who have taken monoamine oxidase inhibitors (MAOIs) within the preceding 14 days.

Precautions:
Sudafed Blocked Nose & Sinus Capsules contains paracetamol; it should not be taken with anything else containing paracetamol. Paracetamol-containing drugs should be given with caution to patients with severe renal or severe hepatic impairment, Raynaud's Phenomenon, and diabetes mellitus. The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease. 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 or 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. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients

with multiple risk factors. Paracetamol has known interactions with domperidone, metoclopramide, and cholestyramine. Please seek medical advice before taking paracetamol-caffeine-phenylephrine in combination with the following drugs: warfarin and other coumarins, drugs that induce hepatic microsomal enzymes (e.g., alcohol, barbiturates, MAOIs, tricyclic antidepressants, amitriptyline), flucloxacillin, sympathomimetics amines, vasodilators, beta-blockers, other hypertensives (including debrisoquine, guanethidine, reserpine, methyldopa), digoxin and cardiac glycosides, ergot alkaloids. This medicine contains less than 1 mmol sodium (23 mg) per 2 capsules, that is to say, it is essentially 'sodium-free'.

Pregnancy and Lactation:

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency. 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 (phenylephrine): 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.

Not known (paracetamol): high anion gap metabolic acidosis.

Not known (caffeine): nervousness, anxiety, irritability, restlessness, excitability, dizziness.

Not known (phenylephrine): 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): 16s £4.58

Legal category: GSL.

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

PL Number: PL 12063/0067.

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