

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.

Sudafed Decongestant Tablets (Pseudoephedrine HCl 60mg) Product Information

Presentation:

Reddish-brown, round, biconvex film-coated tablets, with 'Sudafed' on one side. Tablets contain pseudoephedrine HCl 60mg.

Uses:

Symptomatic relief of allergic rhinitis, vasomotor rhinitis, common cold and influenza.

Dosage:

Adults and children over 12 years: 1 tablet every 4 – 6 hours up to 4 times a day.

Contraindications:

Hypersensitivity to ingredients, severe hypertension or coronary artery disease, with or within 2 weeks of receiving MAOIs. This product is contraindicated in individuals who are concomitantly taking other sympathomimetic decongestants and individuals taking beta blockers

Precautions:

Mild to moderate hypertension, renal impairment, severe hepatic impairment, heart disease, diabetes, hyperthyroidism, elevated intraocular pressure, prostatic enlargement. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. Concomitant use of tricyclic antidepressants, bretylium, betanidine, guanethidine, debrisoquine, methyl dopa, alpha and beta blockers, other sympathomimetic agents. Severe Skin reactions: Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. Ischaemic colitis: Pseudoephedrine should be discontinued and medical advice sought if sudden abdominal pain, rectal bleeding or other symptoms of ischaemic colitis develop. Cases of ischaemic optic neuropathy have been reported with pseudoephedrine. Pseudoephedrine should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs. There have been rare cases of posterior reversible encephalopathy syndrome (PRES) / reversible cerebral vasoconstriction syndrome (RCVS) reported with sympathomimetic drugs, including pseudoephedrine

Pregnancy and Lactation:

This product should not be used during pregnancy or lactation unless the potential benefit of treatment to the mother outweighs the possible risks to the developing foetus or nursing infant.

Side effects:

Very Common: Headache Common: Insomnia, Nervousness, Dizziness, Dry mouth, Nausea Not Known: Hypersensitivity –cross-sensitivity may occur with other sympathomimetics, Anxiety, Euphoric mood, Excitability, Hallucinations, Irritability, Paranoid delusions, Restlessness, Sleep disorder, Cerebrovascular accident, Paraesthesia Posterior reversible encephalopathy syndrome (PRES)/reversible cerebral vasoconstriction syndrome (RCVS), Psychomotor hyperactivity, Somnolence, Tremor, Ischaemic optic neuropathy, Dysrhythmias, Myocardial infarction/myocardial ischaemia, Palpitations, Tachycardia, Hypertension, Ischaemic colitis, Vomiting, Angioedema

Pruritus, Rash, Severe skin reactions, including acute generalised exanthematous pustulosis (AGEP), Dysuria, Urinary retention (in men in whom prostatic enlargement could have been an important predisposing factor)

Please refer to Summary of Product Characteristics for detailed information

RRP (ex VAT): 12s, £3.63

Legal category: P

PL Holder: McNeil Products Ltd., 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG, UK.

PL Number: PL 15513/0024

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