

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

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

Sudafed Decongestant Tablets (pseudoephedrine hydrochloride) Product Information

Presentation:

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

Uses:

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

Dosage:

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

Contraindications:

This product is contraindicated in individuals with known hypersensitivity to pseudoephedrine or to any of its excipients; cardiovascular disease including hypertension, diabetes mellitus, phaeochromocytoma, hyperthyroidism, closed angle glaucoma, severe acute or chronic kidney disease/renal failure. This product is also contraindicated in individuals with concomitant use of other sympathomimetic decongestants, beta-blockers, or monoamine oxidase inhibitors (MAOIs), or within 14 days of stopping MAOI treatment. The concomitant use of MAOIs may cause a rise in blood pressure and/or hypertensive crisis.

Precautions:

This product contains lactose; patients with hereditary problems of galactose intolerance, total lactase deficiency, or glucose malabsorption should not take this medicine. Caution should be exercised when using the product in the presence of severe hepatic impairment or moderate renal impairment and in occlusive vascular disease. Patients with difficulty in urination and/or enlargement of the prostate, or patients with thyroid disease who are receiving thyroid hormones should not take pseudoephedrine unless directed by a physician. This product should be stopped if hallucinations, restlessness, or sleep disturbances occur. Pseudoephedrine has known interactions with the following medicinal products: moclobemide, antihypertensives such as bretylium, betanidine, guanethidine, debrisoquine, methyl dopa, adrenergic neurone blockers and beta blockers, cardiac glycosides, ergotamine and methysergide, appetite suppressants and amphetamine-like psychostimulants, oxytocin, tricyclic antidepressants, and other anaesthetic agents. Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. If signs and symptoms such as pyrexia, erythema, or many small pustules are observed, administration of this medicine should be discontinued, and appropriate measures taken if needed. Some cases of ischaemic colitis have been reported with pseudoephedrine. This product

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. This product should be discontinued if sudden loss of vision or decreased visual acuity such as scotoma occurs. Cases of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS) have been reported with the use of pseudoephedrine-containing products. The risk is increased in patients with severe or uncontrolled hypertension, or with severe acute or chronic kidney disease/renal failure. Pseudoephedrine should be discontinued, and immediate medical assistance sought if the following symptoms occur: sudden severe headache or thunderclap headache, nausea, vomiting, confusion, seizures and/or visual disturbances.

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. There are no adequate and well-controlled studies in pregnant women. Pseudoephedrine is excreted in breast milk in small amounts, but the effect of this on breast-fed infants is not known.

Side effects:

Very common: headache

Common: insomnia, nervousness, dizziness, dry mouth, nausea

Not known: hypersensitivity (cross-sensitivity 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): 12's, £4.17

Legal category: P

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

PL Number: PL 15513/0024

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