

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 Liquid (Pseudoephedrine Hydrochloride 30mg/5ml) Product Information

Presentation:

Liquid containing 30mg per 5ml of pseudoephedrine Hydrochloride.

Uses:

For the relief of nasal congestion and congestion of mucous membranes of the upper respiratory tract associated with the common cold.

Dosage:

Adults and children over 12 years: 10ml every 4-6 hours up to 4 times a day. Children 6-12 years: 5ml every 4-6 hours up to 4 times a day

Contraindications

This product is contraindicated in individuals with known hypersensitivity to pseudoephedrine or to any of the excipients. Children under 6 years, hypersensitivity, cardiovascular disease including hypertension, with or within 2 weeks of receiving MAOIs and/or RIMAs, diabetes mellitus, phaeochromocytoma, hyperthyroidism, closed angle glaucoma, severe renal impairment, concomitant use of other sympathomimetic decongestants or beta blockers. The concomitant use of MAOIs may cause a rise in blood pressure and/ or hypertensive crisis.

Precautions:

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. Caution should be exercised when using the product in the presence of severe hepatic impairment or moderate to severe renal impairment, and in occlusive vascular disease. Product should be stopped if patients experience hallucinations, restlessness, sleep disturbances. Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine containing products. 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.

Each 5 ml of this medicine contains 3.5 g of sucrose. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. This medicine contains methyl hydroxybenzoate (E218) and therefore may cause allergic reactions (possibly delayed). This medicine contains Ponceau 4R (E124) and therefore may cause allergic reactions. This medicine contains 3.73 mg propylene glycol in each 5ml. This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to

say essentially 'sodium-free'.

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 breastfeeding 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/myocardia 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)

RRP (ex VAT): 100ml £3.35

Legal category: P

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

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