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 Liquid (pseudoephedrine hydrochloride) Product Information

Presentation:
Liquid containing 30 mg per 5 ml 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: 10 ml every 4 to 6 hours, up to 4 times a day.
Children 6 to 12 years: 5 ml every 4 to 6 hours, up to 4 times a day. Not to be used for more than five days without the advice of a doctor.
Contraindications
This product is contraindicated in children under the age of 6 years. It is also contraindicated in individuals with known hypersensitivity to pseudoephedrine or to any of the excipients; cardiovascular disease including hypertension, diabetes mellitus, phaeochromocytoma, hyperthyroidism, closed angle glaucoma, severe acute or chronic kidney disease/renal failure. This product should not be used by individuals who are concomitantly taking beta blockers, or other sympathomimetic decongestants, and in individuals who are taking, or who have taken monoamine oxidase inhibitors (MAOIs) within the preceding 14 days. The concomitant use of MAOIs and pseudoephedrine-containing products may result in a rise in blood pressure and/or hypertensive crisis. This product contains 3.5 g of sucrose per 5 ml; therefore, patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. It also contains methyl hydroxybenzoate (E 218) and Ponceau 4R (E 124), both of which may cause allergic reactions.
Precautions:
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, urinary retention and/or prostatic hyperplasia, patients with thyroid disease who are receiving thyroid hormones are advised to consult a physician before using this product. This 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. This acute pustular eruption may occur within the first 2 days of treatment, with fever, and numerous, small, mostly non-follicular pustules arising on a widespread oedematous erythema and mainly

localized on the skin folds, trunk, and upper extremities. Patients should be carefully monitored. 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. 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.
This product contains the following excipients:

- 3.5 g of sucrose per 5 ml, which should be taken into account in patients with diabetes mellitus.
- 3.73 mg of propylene glycol in each 5 ml.
- 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. There are no adequate and well-controlled studies of pseudoephedrine use 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): 100 ml, £3.99
Legal category: P
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG.
PL Number: PL 15513/0023
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