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.

Benylin Mucus Cough plus Decongestant Syrup (Guaifenesin, Pseudoephedrine) Product Information

Presentation:

Orange-red syrup containing 100 mg Guaifenesin and 30mg Pseudoephedrine per 5 ml.

Uses:

Symptomatic relief of upper respiratory tract disorders with productive cough.

Dosage:

Adults and children over 12 years: 10 ml every 4-6 hours up to four times daily.

Contraindications:

Known hypersensitivity to ingredients; hypertension; coronary artery disease; with or within 2 weeks of receiving MAOIs; use in children under 12 years. This product is contraindicated in individuals who are concomitantly taking other sympathomimetic decongestants and individuals taking beta blockers. This product is contraindicated in individuals with diabetes mellitus, closed angle glaucoma, hyperthyroidism, phaeochromocytoma or severe renal impairment. The concomitant use of pseudoephedrine and this type of product may cause a rise in blood pressure and/ or hypertensive crisis

Precautions:

Patients with thyroid disease who are receiving thyroid hormones should not take pseudoephedrine unless directed by a physician. Patients with the following conditions should be advised to consult a physician before using this product: difficulty in urination and/or enlargement of the prostate; a respiratory condition such as emphysema, chronic bronchitis or acute or chronic bronchial asthma.This product should be not used for persistent or chronic cough, such as occurs with asthma, or emphysema where cough is accompanied by excessive secretions, unless directed by a physician.

Patients should be advised to consult a physician if their cough lasts for more than 5 days or comes back, or is accompanied by a fever, rash or persistent headache. Caution should be exercised when using the product in the presence of severe hepatic impairment or moderate to severe renal impairment (particularly if accompanied by cardiovascular disease), Product should be stopped if hallucinations, restlessness or sleep disturbances occur.

Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. Some cases of ischaemic colitis have been reported with pseudoephedrine. Pseudoephedrine should be discontinued. There

have been rare cases of posterior reversible encephalopathy syndrome (PRES) / reversible cerebral vasoconstriction syndrome (RCVS) reported with sympathomimetic drugs, including pseudoephedrine. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine. This product contains Ponceau 4R (E124) red colouring and sunset yellow (E110) which may cause allergic reactions. This product contains Methyl Hydroxybenzoate (E 218) and Propyl Hydroxybenzoate (E 216) which may cause allergic reactions (possibly delayed). A dose of 10 ml of this medicine administered to a child 12 years of age and weighing 40 kg or an adult weighing 70 kg would result in exposure to 10 or 6 mg/kg of ethanol respectively which may cause a rise in blood alcohol concentration (BAC) of less than 2.5 mg/100 ml. For comparison, for an adult drinking a glass of wine or 500 ml of beer, the BAC is likely to be about 50 mg/100 ml. Co-administration with medicines containing e.g. propylene glycol or ethanol may lead to accumulation of ethanol and induce adverse effects. Severe Skin reactions: Severe skin reactions such as acute generalized exanthematous pustulosis (AGEP) may occur with pseudoephedrine-containing products. ischaemic col itis: 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 breastfeeding infant.

Side effects:

Very common: Headache Common: Insomnia, Nervousness, Dizziness, Dry mouth, Nausea Not Known: Anxiety, Ischaemic optic neuropathy, Hypersensitivity (Cross-sensitivity may occur with other sympathomimetics), Euphoric mood, Excitability, Hallucinations, Irritability, Paranoid delusions, Restlessness, Sleep disorder, Cerebrovascular accident Posterior reversible encephalopathy syndrome (PRES)/reversible cerebral vasoconstriction syndrome (RCVS), Psychomotor hyperactivity, Somnolence, Dysrhythmias, Myocardial infarction/myocardial ischaemia, Palpitations, Tachycardia, Hypertension, Abdominal pain, Diarrhoea, Ischaemic colitis, Vomiting, Angioedema, Pruritus, Rash, Severe skin reactions, including acute generalised exanthematous pustulosis (AGEP), Urticaria, Dysuria, Urinary Retention (in men in whom prostatic enlargement could have been an important predisposing factor), Tremor, Paraesthesia

Please refer to Summary of Product Characteristics for detailed information

RRP (ex-VAT): 100ml: 4.19

Legal category: P

PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire
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PL Number: 15513/0022

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