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 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. Each 5ml also contains: Sucrose 3g, Methyl Hydroxybenzoate (E 218) 5mg, Propyl Hydroxybenzoate (E 216) 0.5mg, Ethanol 96 %v/v 190mg, Ponceau 4R (E 124) 0.25mg, Sunset Yellow (E 110) 0.25mg, Benzyl alcohol 0.02 mg

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:

This product is contraindicated in children under the age of 12 years.

This product is also contraindicated in individuals with known hypersensitivity to ingredients; cardiovascular disease including hypertension, diabetes mellitus, closed angle glaucoma, hyperthyroidism, phaeochromocytoma or severe renal impairment. This product is contraindicated in individuals taking beta blockers, concomitantly taking other sympathomimetic decongestants, and individuals who are taking, or who have taken monoamine oxidase inhibitors within the preceding 14 days. 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), or occlusive vascular 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 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. Pseudoephedrine should be discontinued, and medical advice sought immediately, when onset of severe headache, nausea, vomiting, and visual disturbances occur.
Contains the following excipients:

- 3g of sucrose per 5ml which should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.
- Less than 1mmol sodium (23mg) per 5ml, that is to say essentially 'sodium free.'
- 0.02 mg benzyl alcohol in each 5 ml. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding.
- Ponceau 4R (E 124) red colouring and sunset yellow (E 110) which may cause allergic reactions
- Methyl Hydroxybenzoate (E 218) and Propyl Hydroxybenzoate (E 216) which may cause possibly delayed allergic reactions.
- 190 mg of alcohol (ethanol) in each 5 ml. The amount in 5 ml of this medicine is equivalent to less than 5 ml beer or 2 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Please refer to Summary of Product Characteristics for detailed information

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
RRP (ex-VAT): 100ml: £4.49
Legal category: P
PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe, BuckinghamshireHP12 4EG, UK
PL Number: 15513/0022
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