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**Adverse events should also be reported to McNeil Products Limited on 01344 864 042.**

## **Benylin Mucus Cough Max Menthol Flavour 100 mg/5 ml Oral Solution (Guaifenesin) Product Information**

### **Presentation:**

Red syrup containing 100 mg Guaifenesin per 5 ml.

### **Uses:**

To help loosen phlegm and thin bronchial secretions associated with productive cough.

### **Dosage:**

Adults and children over 12 years: 10 ml four times daily, max 40ml daily. Not recommended in children under 12 years.

### **Contraindications:**

Hypersensitivity to the active substance or to any of the excipients

### **Precautions:**

Do not use in persistent or chronic cough, e.g. asthma, or cough accompanied by excessive secretions; caution in severe renal or hepatic impairment; rare hereditary problems of fructose intolerance, glucose galactose malabsorption. Concomitant use of cough suppressants not recommended. This product contains ethanol. This product contains Ponceau 4R (E124) which may cause allergic reactions. This product contains sodium and this should be taken into consideration by those on a controlled sodium diet. This medicinal product contains 10 mg of benzoate salt in each 10 ml dose. This medicinal product may contain very trace amounts of glucose. A dose of 10 ml of this medicine administered to a child 12 years of age and weighing 35 kg would result in exposure to 10.9 mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 1.81 mg/100 ml. A dose of 10 ml of this medicine administered to an adult weighing 70 kg would result in an exposure of 5.4 mg/kg of ethanol which may cause a rise in blood alcohol concentration (BAC) of about 0.9 mg/100 ml. (see Appendix 1 of report EMA/CHMP/43486/2018). 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, in particular in young children with low or immature metabolic capacity. This medicinal product contains less than 1 mmol sodium (23 mg) per 10 ml dose, that is to say essentially 'sodium-free'. Medical monitoring is required in patients with impaired renal or hepatic functions because various adverse events attributed to propylene glycol have been reported such as renal dysfunction (acute tubular necrosis), acute renal failure and liver dysfunction. This medicinal product contains macrogol glycerol hydroxystearate 40. It may cause stomach upset and diarrhoea.

### **Pregnancy and Lactation:**

Benylin Mucus Cough Max Menthol Flavour 100 mg/5 ml

Oral Solution is not recommended during pregnancy and in women of childbearing potential not using contraception. Breast-feeding Guaifenesin is excreted in breast milk in small amounts. There is insufficient information on the effects of guaifenesin in newborns/infants. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from Benylin Mucus Cough Max Menthol flavour 100 mg/5 ml Oral Solution therapy, taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman. This medicinal product contains 2003.5 mg propylene glycol in each 10 ml dose. While propylene glycol has not been shown to cause reproductive or developmental toxicity in animals or humans, it may reach the foetus and was found in milk. As a consequence, administration of propylene glycol to pregnant or lactating patients should be considered on a case by case basis.

**Side effects:**

*Frequency not known:* Abdominal pain upper, diarrhoea, nausea, vomiting, hypersensitivity reactions including pruritus, urticaria and rash.

**RRP (ex-VAT):** 150ml £5.09

**Legal category:** GSL.

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

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