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.

Benylin Children's Chesty Coughs (guaifenesin) Product Information

Presentation:

Syrup containing 50 mg guaifenesin per 5 ml.

Indications:

Symptomatic relief of acute productive (chesty) coughs.

Dosage and Administration:

Children 6 to 12 years: 10 ml 4 times daily, max daily dose 40ml.

Contraindications:

Use in children under 6 years. Hypersensitivity.

Precautions:

Not to be used for more than 5 days without the advice of a doctor. Parents and carers should seek medical attention if the child's condition deteriorates during treatment; do not use with cough suppressants; caution in chronic cough or asthma; caution in severe renal or hepatic impairment. See SPC for further details. Excipient warning: This medicine contains 5.05g sorbitol in each 10 ml dose. The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly. Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product. Sorbitol may cause gastrointestinal discomfort and mild laxative effect. This medicine contains 25.2 mg benzoate salt in each 10 ml dose. This medicine contains 0.1 mg benzyl alcohol in each 10 ml dose. Benzyl alcohol may cause allergic reactions. This medicine must be used with caution in patients with renal or hepatic impairment, or in patients who are pregnant or breast-feeding, because of the risk of accumulation and toxicity (metabolic acidosis).

Pregnancy and Lactation:

This medicine must be used with caution in patients who are pregnant or breast-feeding. BENYLIN Children's Chesty Coughs is not recommended during pregnancy and in women of childbearing potential not using contraception.

Side effects:

<u>Not known</u>: Hypersensitivity reactions (hypersensitivity, pruritus, urticaria), rash, abdominal pain upper, diarrhoea, nausea, vomiting.

Please refer to Summary of Product Characteristics for detailed information.

RRP (ex-VAT): 125 ml, £4.66

Legal Category: P

PL Holder: McNeil Products Ltd, 50 – 100 Holmers Farm Way, High Wycombe,

Buckinghamshire, HP12 4EG

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