

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 Herbal Cough & Cold Sugar Free Syrup (*Pelargonium*, Sorbitol, Maltitol) Product Information

Presentation:

A dark red syrup containing 20 mg of dry extract from *Pelargonium* root (*Pelargonium sidoides* DC and/or *Pelargonium reniforme* Curt., radix) per 2.5ml in extraction solvent ethanol 11% (m/m). Also contains 893mg of sorbitol (E 420) and 893mg of maltitol (E 965) per 2.5ml.

Uses:

Traditional herbal medicinal product used to relieve of symptoms associated with the common cold such as coughs, sore throat and blocked or runny nose. Based on traditional use only.

Dosage:

Adults, the elderly, and children over 12 years: Using the graduated measuring spoon provided, take 2.5ml, three times per day. Children between 6 to 12 years: Using the graduated measuring spoon provided, take 2.5ml, two times per day. Do not use for more than 10 days.

Contraindications:

Known hypersensitivity to *Pelargonium* root or any of the product's excipients. Not for use in patients with severe hepatic or renal disease and in patients with rare hereditary problems of fructose intolerance.

Precautions:

Do not exceed the stated dose. The use of this product in children under 6 years of age has not been established due to the lack of clinical data.

Hepatotoxicity and hepatitis were reported in association with the medicinal product.

This product should be discontinued immediately in the occurrence of signs of hepatotoxicity, such as fatigue, anorexia, yellowing of the skin and eyes, severe stomach pain with nausea and vomiting, or dark urine. Consult with a qualified healthcare professional is advised. Moreover, the presence of any of following also warrant further consultation: worsening of symptoms, lack of improvement of symptoms after one week of intake, fever, shortness of breath, and blood in the sputum.

The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be considered. The content of sorbitol in medicinal products for oral use may also affect the bioavailability of other medicinal products for oral use administered concomitantly. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

See SPC for further precautions.

Pregnancy and Lactation:

Safety during pregnancy and lactation has not been established. In the absence of sufficient data use during pregnancy and lactation is not recommended. Studies on the effects on fertility have not been performed.

Side effects:

Very rare: serious hypersensitivity reactions (e.g., swelling of the face, dyspnoea, and decrease in blood pressure), diarrhoea, epigastric discomfort, nausea or vomiting, dysphagia, mild nasal and gingival bleeding, dermatitis, rash, rash erythematous, exanthema, urticaria, pruritus of skin and mucous membranes.

Not known: Hepatotoxicity, hepatitis, liver dysfunction of different origin, dizziness, flushed skin.

RRP (ex-VAT): £ 6.50

Legal category: GSL

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