Adverse events should be reported. Reporting forms and information can be found at www. https://yellowcard.mhra.gov.uk/

Adverse events should also be reported to McNeil Products Limited on 0808 238 9999.

## Benylin Herbal Chesty Coughs Sugar Free Syrup (Ivy leaf, Sorbitol) Product Information

**Presentation:** Brown, opalescent liquid containing 33mg of extract (as dry extract) of lvy leaf (*Hedera helix L.*) (DER 4-8:1). Extraction solvent ethanol 30% m/m and 2832mg of Sorbitol per 4ml.

**Uses:** Used to relieve chesty coughs associated with the common cold, based on traditional use only.

**Dosage:** Adults, the elderly, and children aged 12 years and over. The recommended dose is 4 ml of syrup two to three times daily using the graduated measuring spoon provided.

**Contraindications:** Hypersensitivity to the active substance or to any of the excipients.

**Precautions:** Do not exceed the stated dose. The use of this product in children under 12 years of age is not recommended because data are not sufficient and medical advice should be sought. If dyspnoea, fever or purulent sputum occurs, a doctor should be consulted. If the symptoms worsen, or persist longer than one week during the use of Benylin Herbal Chesty Coughs Sugar Free Syrup, a doctor or qualified healthcare practitioner should be consulted. Concomitant use with antitussives such as codeine or dextromethorphan is not recommended without medical advice. Caution is recommended in patients with gastritis or gastric ulcer. Benylin Herbal Chesty Coughs Sugar Free Syrup contains sorbitol. 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. Each 4ml of syrup contains 2832 mg of sorbitol (E420). Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

**Pregnancy and lactation:** Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

**Side-effects:** Gastrointestinal reactions (nausea, vomiting, and diarrhoea) have been reported. The frequency is not known. Allergic reactions (urticaria, skin rash, dyspnoea) have been reported. The frequency is not known.

RRP (ex-VAT): £5.20 Legal category: GSL. **PL holder:** McNeil Products Limited, 50 – 100 Holmers Farm Way, High Wycombe,

Buckinghamshire, HP12 4EG. **PL Number:** THR 15513/0185 **Date of preparation:** 14 Apr 2022