

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 Mucus Cough & Cold All in One Relief Tablets or Sudafed Mucus Relief Triple Action Cold & Flu Tablets (Paracetamol, Guaifenesin, Phenylephrine hydrochloride) Product Information

Presentation: Tablets containing 250mg paracetamol, 100mg guaifenesin, 5mg phenylephrine hydrochloride.

Uses:

Symptomatic relief of cold and flu, including aches and pains, headache, blocked nose, sore throat, chills and chesty cough.

Dosage:

Adults and children 12 years and over: 2 tablets every 4 hours as required. Do not take more than 8 tablets in 24 hours. Children under 12 years: Not recommended.

Contraindications:

Hypersensitivity to any of the ingredients, hepatic or severe renal impairment, hypertension, hyperthyroidism, diabetes, heart disease, glaucoma, including closed angle glaucoma, urinary retention, phaeochromocytoma, patients receiving other sympathomimetic drugs, or those taking tricyclic antidepressants or beta-blocking drugs, and those patients who are taking or have taken, within the last two weeks, monoamine oxidase inhibitors. Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended. Avoid in patients with prostatic enlargement.

Precautions:

Patients suffering from chronic cough or asthma, enlargement of the prostate gland, occlusive vascular disease and cardiovascular disease should consult a physician before taking the product. Patients should stop using the product and consult a healthcare professional if cough lasts for more than 5 days or comes back, or is accompanied by a fever, rash or persistent headache. Not to take with a cough suppressant. Caution in patients with circulatory disorders, and prostatic hypertrophy. Use may give rise to insomnia, nervousness, hyperpyrexia, tremor, and epileptiform convulsions. Long-term use not recommended. See SPC for further information.

Pregnancy and Lactation: This product should not be used during pregnancy or breastfeeding without medical advice.

Side effects:

Allergic reactions, angioedema, anaphylactic reactions, dyspnoea, nausea, vomiting, abdominal discomfort, diarrhoea, rash, urticaria, thrombocytopenia, agranulocytosis, bronchospasm, hepatic dysfunction, acute pancreatitis, nervousness, irritability, restlessness, excitability, headache, dizziness, insomnia, increased blood pressure, mydriasis, acute angle closure glaucoma, tachycardia, and palpitations. Urinary

retention has been reported (unknown frequency). This is most likely to occur in men with an enlarged prostate.

Price (ex-VAT): 16s: £4.64.

Legal category: GSL.

PL holder: Wrafton Laboratories Ltd (T/A Perrigo), Braunton, Devon. EX33 2DL.

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