

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:

This product is contraindicated in individuals with known hypersensitivity to paracetamol, guaifenesin, phenylephrine, or to any of the product's excipients; hypertension, cardiovascular disorders, heart disease, severe hepatic impairment, severe renal impairment, hyperthyroidism, diabetes mellitus, pheochromocytoma, glaucoma including closed angle glaucoma, urinary retention, and prostatic enlargement. This product should not be used by individuals who are concomitantly taking beta blockers or other sympathomimetics (such as decongestants, appetite suppressants, amphetamine-like psychostimulants), and in individuals who are taking, or who have taken monoamine oxidase inhibitors (MAOIs) within the preceding 14 days.

Precautions:

Benylin Mucus Cough & Cold All in One Relief Tablets or Sudafed Mucus Relief Triple Action Cold & Flu Tablets is not recommended for use in children under 12 years of age. 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. 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 discontinue 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.

Do not take this product while on other cough suppressants. Caution in patients with circulatory disorders, and prostatic hypertrophy. Use may give rise to insomnia, nervousness, hyperpyrexia, tremor, and epileptiform convulsions. Long-term use is not recommended.

Please refer to Summary of Product Characteristics for detailed information.

Pregnancy and Lactation:

This product contains paracetamol and phenylephrine and 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, Stevens Johnson syndrome, toxic epidermal necrolysis, bronchospasm, hepatic dysfunction, acute pancreatitis, nervousness, irritability, restlessness, excitability, headache, dizziness, insomnia, increased blood pressure, mydriasis, acute angle closure glaucoma, tachycardia, palpitations, hypersensitivity including cross-sensitivity with other sympathomimetics.

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

Please refer to Summary of Product Characteristics for detailed information.

Price (ex-VAT): 16s: £4.64.

Legal category: GSL.

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

PL Number: 12063/0112.

Date of preparation: 17 April 2023