

pharmaniaga®

Salbutamol


Expectorant

DESCRIPTION

Clear, colourless, raspberry flavoured liquid.

COMPOSITION

Each 5 mL contains : Salbutamol (as sulphate) 1 mg and Guaiphenesin 50 mg.
Preservative : Sodium benzoate 0.10% w/v.

ACTIONS

Salbutamol is a direct-acting sympathomimetic agent with a relatively selective action on beta₂-adrenoceptors. It is used as a bronchodilator. Guaiphenesin is reported to reduce the viscosity of tenacious sputum and used as an expectorant.

Salbutamol is readily absorbed from the gastro-intestinal tract. It is subject to first pass metabolism in the liver and possibly in the gut wall; about a half is excreted in the urine as an inactive sulphate conjugated following oral administration (the rest being unchanged salbutamol).

Guaiphenesin is absorbed from the gastro-intestinal tract. It is metabolised and excreted in the urine.

INDICATIONS

Productive cough and wheezing associated with asthma, pneumonia, flu and acute respiratory infections.

CONTRAINDICATIONS

Intolerance to salbutamol or guaiphenesin.

ADVERSE REACTIONS

Salbutamol may cause fine tremors of skeletal muscle (particularly the hands), palpitations, and muscle cramps. Slight tachycardia, tenseness, headaches and peripheral vasodilation have been reported after large doses.

Gastro-intestinal discomfort has occasionally been reported with guaiphenesin. Very large doses can cause nausea and vomiting.

PRECAUTIONS

Caution should be exercised in patients who are particularly susceptible to effects of sympathomimetics particularly those with hyperthyroidism. Great care is also needed in patients with cardiovascular disease such as ischaemic heart disease, arrhythmia or tachycardia, occlusive vascular disorders including arteriosclerosis, hypertension or aneurysms. Anginal pain may be precipitated in patients with angina pectoris. Care is also required when sympathomimetic agents are given to patients with diabetes mellitus or closed-angle glaucoma.

Pregnancy

Adequate and well-controlled studies in humans have not been done for both salbutamol and guaiphenesin. However, some animal studies in mice and rabbits have shown abnormalities and malformations to the foetus for salbutamol.

Breast feeding

Although it is not known if salbutamol is excreted in breast milk, problems in humans have not been documented. However, some animal studies have shown potential tumourgenicity. Problems in humans have not been documented for guaiphenesin.

Tocolysis

Serious adverse reactions including death have been reported after administration of salbutamol to women in labor. In the mother, these include increased heart rate, transient, hyperglycaemia, hypokalaemia, cardiac arrhythmias, pulmonary oedema and myocardial ischaemia. Increased fetal heart rate and neonatal hypoglycaemia may occur as a result of maternal administration.

DRUG INTERACTION

Corticosteroids : Adverse metabolic effects of high doses of salbutamol may be exacerbated by concomitant administration of high dose of corticosteroids. Patients should be monitored carefully when the two forms of therapy are used together.

Beta-blockers : Propranolol and other beta-adrenoceptor blocking agents antagonise the effects of salbutamol.

Aminophylline or other xanthines : The effects of salbutamol, such as hypokalaemia, may also be enhanced by concomitant administration.

Diuretics : Hypokalaemia effects of salbutamol may be enhanced.

Digitalis : Hypokalaemia associated with high doses of salbutamol may result in increased susceptibility to cardiac arrhythmias.

DOSAGE AND ADMINISTRATION

To be taken two or three times daily.

Adults : 10 - 20 mL

Children : 5 - 10 mL

OVERDOSAGE

Symptoms : Extended effects of the adverse reactions.

Treatment : 1. Gastric lavage.

2. Administration of a cardioselective beta-adrenergic blocker, if necessary for cardiac arrhythmias; however, it should be used with caution because it could induce severe bronchospasm or an asthmatic attack.

ROUTE OF ADMINISTRATION

Oral.

STORAGE CONDITIONS

Store below 30°C.

Protect from light.

Keep container tightly closed.

SHELF LIFE

Product should not be used beyond the expiry date imprinted on the product packaging.

PRESENTATION

Bottles of 60 mL, 90 mL and 120 mL.

Date of revision: 02 April 2026

PRODUCT REGISTRATION HOLDER:

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MANUFACTURER

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