Salbutamol + Guaifenesin

Broncaire Expectorant

1 mg / 50 mg per 5 mL
Syrup

Bronchodilator / Expectorant

PRODUCT DESCRIPTION:
Clear, almost colorless with menthol-flavored solution.

FORMULATION:
Each 5 mL contains:
Salbutamol sulfate eq. to Salbutamol 1 mg
Guaifenesin 50 mg

PHARMACODYNAMICS:
Salbutamol is a $beta_2$-adrenergic stimulant which has high selective action on the receptors in the bronchial muscles, leading to bronchodilation. It has little or no action on the cardiac receptors.
Oral administration of Guaifenesin facilitates expectoration by reducing mucus viscosity.
Pulmonary ventilation cannot be achieved simply by relieving bronchospasm when there is excessive mucus. Hence, mucus obstruction has to be removed. Thus, the salbutamol guaifenesin combination (Broncaire Expectorant) is designed to decrease mucus viscosity and to improve pulmonary ventilation.

PHARMACOKINETICS:
Salbutamol sulfate is rapidly and well absorbed following oral administration. Peak plasma concentrations occur within about 2 hours following administration of oral solution. Salbutamol crosses the blood-brain barrier, reaching the brain at concentrations that are approximately 5% of plasma concentrations.
Salbutamol apparently crosses the placenta, but it is not known whether salbutamol is distributed into milk.
After oral administration, the half-life of salbutamol is 5-6 hours. Salbutamol is extensively metabolized in the liver, mainly to salbutamol 4'-O sulfate which has little or no beta-adrenergic stimulating effect and no beta-adrenergic blocking effect. Salbutamol and its metabolites are rapidly excreted in urine and feces. About 75% of single dose is excreted in urine within 72 hours, mainly as the major metabolite; about 4% of the dose is excreted in feces. Guaifenesin is readily absorbed from the gastrointestinal tract and rapidly metabolized and excreted in the urine. Guaifenesin has a plasma half-life of 1 hour. The major urinary metabolite is beta-(2-methoxyphenoxy) lactic acid.

INDICATIONS:
For the relief of bronchospasm in all types of bronchial asthma, chronic bronchitis and emphysema.

DOSAGE AND ADMINISTRATION:

Adults and children over 12 years	:	2-3 tsp 2-3 times daily
Children, 6 to 12 years	:	1-2 tsp 2-3 times daily
Children, up to 6 years	:	1 tsp 2-3 times daily

CONTRAINDICATIONS:
It is contraindicated in patients with a history of hypersensitivity to any of the components. Salbutamol is not contraindicated in patients under treatment with MAOIs. Although the tablets are used in the management of uncomplicated premature labor, salbutamol preparations should not be used for threatened abortion during the first and second trimesters of pregnancy.

PRECAUTIONS:
Salbutamol should be administered cautiously to patients suffering from thyrotoxicosis.
Use in pregnancy: As with any other drug, avoid its use during the first trimester of pregnancy.

ADVERSE DRUG REACTION:
Adverse effects associated with salbutamol are as follows:
Common:
Neuromuscular & skeletal – tremor
Central nervous system - nervousness in children aged 2-6 years and insomnia in children aged 6-12 years receiving 4-12 mg every 12 hours.
Rare:
Central nervous system - headache, dizziness
Gastrointestinal - nausea, vomiting, dry mouth, dyspepsia
Respiratory - bronchospasm, cough
Otic – otitis media, vertigo
Miscellaneous – allergic reactions
Adverse effects associated with guaifenesin are rare.
Central nervous system – dizziness, drowsiness, headache
Dermatologic – rash
Endocrine & metabolic – uric acid levels decreased
Gastrointestinal – nausea, stomach pain, vomiting

OVERDOSAGE AND TREATMENT:
Symptoms
Overdosage of oral salbutamol produces symptoms that are mainly extensions of common adverse effect of salbutamol (e.g. palpitations, tachycardia, transient arrhythmias, heart block, angina, hypokalemia, nausea, vomiting, insomnia, anxiety, nervousness, drowsiness, muscle cramps, headache, sweating, tremor). Delirium, convulsions, collapse, and coma may occur.
Overdosage with guaifenesin is unlikely to produce toxic effects since its toxicity is low.
Treatment
The preferred antidote for overdosage with salbutamol is a cardioselective beta-blocking agent, but beta-blocking drugs should be used with caution in patients with a history of bronchospasm.
In severe cases of guaifenesin overdosage, treatment should be aimed at reducing further absorption of the drug. Gastric emptying is recommended as soon as possible after ingestion. Treatment is symptomatic and supportive.

DRUG INTERACTIONS:
Non-selective beta-blocking drugs, e.g. propranolol, should not be prescribed together with salbutamol.

ADR REPORTING STATEMENT:
"For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph". Seek advice from a healthcare professional at the first sign of any adverse drug reaction.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

STORAGE:
Store at temperatures not exceeding 30°C.
Keep out of reach of children.

Availability	Reg. No.	Date of Authorization	
		1st	Renewal
Bottles of 60 mL	DR-XY17334	19 Feb 1998	14 Aug 2027

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