Primera

GUAIFENESIN SALBUTAMOL

BRONCHOPRIME

50 mg/1 mg per 5 mL SYRUP
EXPECTORANT/SELECTIVE BETA-2-ADRENORECEPTOR AGONIST

Rx

FORMULATION:
Each 5 mL (1 teaspoonful) contains:
Guaifenesin…….....…….....……50 mg
Salbutamol (as sulfate) …….....……1 mg

PRODUCT DESCRIPTION:
Guaifenesin + Salbutamol 50 mg/1 mg per 5 mL Syrup (Bronchoprime) is clear bluish violet colored syrup with a sweet grape fruit taste.

PHARMACODYNAMICS:
Guaifenesin possesses mucolytic properties. Mucolytics are agents that alter the structure of mucus to decrease its viscosity and therefore facilitate its removal by ciliary action or expectoration. Although mucolytics have been shown to affect sputum viscosity and structure, and patients have reported alleviation of their symptoms, no consistent improvement has been demonstrated in lung function. Guaifenesin is reported to reduce viscosity of tenacious sputum and is used as an expectorant.
Salbutamol is a direct acting sympathomimetic agent with predominantly beta-adrenergic activity and selective action on beta 2 receptors. It is used as a bronchodilator. It has more prolonged action than isoprenalin and as a predominantly beta 2 stimulant, has a bronchodilating action relatively more prominent than its effect on the heart. An additional beneficial effect of salbutamol is its action on the uterus as a relaxant, the uterine muscles as we all know contract under beta adrenergic stimulation. Thus it has gained popularity among obstetricians for controlling premature labor. However, a relative contraindication to its used is among pregnant patients with vaginal bleeding because it may cause pulmonary edema.

PHARMACOKINETICS:
Guaifenesin rapidly well absorbed from the gastrointestinal tract. Guaifenesin has a plasma half life of approximately 1 hour and is rapidly metabolized and excreted in urine.Salbutamol is readily absorbed from the gastrointestinal tract after given by oral administration. Salbutamol's onset of action is within 30 minutes peaks in 2 to 3 hours and persists for 6 hours after a dose; Salbutamol has a half-life of 4 to 6 hours. It is metabolized in the liver and converted to the inactive Salbutamol 4'-O-sulfate (phenolic sulfate) which is also excreted primarily in the urine. Salbutamol and its metabolites are excreted via urine and feces. After oral administration, Salbutamol is excreted within 72 hours mainly as a major metabolite, and 4-5% is excreted via feces. Salbutamol is bound to plasma proteins to the extent of 10%, after oral administration, it is absorbed in the gastrointestinal tract and undergoes to first pass metabolism to phenolic sulfate. Both the conjugate and the drug are excreted primarily in the urine. The bioavailability of salbutamol is about 50% when given by oral administration.

INDICATIONS:
Respiratory disorders complicated by bronchospasm and excessive secretion of tenacious mucus, bronchial asthma, chronic bronchitis and emphysema.

DOSAGE AND ADMINISTRATION:
6-12 years old: 2 teaspoonfuls (10 mL) to be taken two or three times a day.
2-6 years old: 1 teaspoonful (5 mL) to be taken two or three times a day or as prescribed by the physician.

CONTRAINDICATIONS:
Hypersensitivity reactions to any ingredient of the product.

PRECAUTIONS:
Sympathomimetics may produce a wide range of adverse effects, most of which mimic the result of excessive stimulation of the sympathomimetic nervous system. Clinically, this is manifested by confusion, irritability, tremor, insomnia and restlessness. Appetite may be reduced and nausea and vomiting may occur.

PREGNANCY AND LACTATION:
Pregnancy
They have rare various cases of report of congenital anomalies such as cleft palate and limb defects in the offspring of patients treated with salbutamol. Drug administration of salbutamol during pregnancy should only be considered if the expected benefit to the mother is beyond than any possible risk to the fetus.
Lactation
Salbutamol may be secreted in breast milk, do not administer to breastfeeding women, unless it is prescribed by the physician. The expected benefit to the drug is beyond than any potential risk to the baby.

DRUG INTERACTIONS:
Salbutamol + Non selective beta blockers (Propranolol) should not be prescribed together; it may inhibit the effect of Salbutamol.
Concurrent use of Monoamine oxidase inhibitors and Tricyclic Antidepressant may increase the risk of cardiac arrhythmia, tachycardia and may increase or decrease blood pressure.

ADVERSE DRUG REACTIONS:
Fine tremor of skeletal muscle, feeling of muscle tension, peripheral vasodilation, tachycardia, headache, transient muscle cramps, hyperactivity in children, risk in dental caries.

OVERDOSE AND TREATMENT:
Guaifenesin gastrointestinal discomfort, nausea, vomiting and urolithiasis have occasionally been reported when taking in large doses.
Salbutamol signs and symptoms of overdose may include the following undesirable effects (headache, insomnia, tachycardia, dry mouth, nausea, palpitations, and tremors). The preferred antidote for over dosage with salbutamol is a cardio selective beta blocking agent. However, cardio selective beta blocking drugs should be used with caution in patients with a history of bronchospasm. Hypokalemia may occur following overdose with salbutamol. Serum potassium levels should be monitored.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

AVAILABILITY:
Amber Glass Bottle x 60 mL (Box of 1's)

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

ADR REPORTING STATEMENT:
"For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph".
Seek medical attention immediately at the first sign of any adverse drug reaction.

REGISTRATION NUMBER:
Guaifenesin + Salbutamol 50 mg/1 mg per 5 mL Syrup *(Bronchoprime)*: DR-XY27887

DATE OF FIRST AUTHORIZATION:
Guaifenesin + Salbutamol 50 mg/1 mg per 5 mL Syrup *(Bronchoprime)*: September 27, 2002

DATE OF REVISION OF PACKAGE INSERT:
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