GUAIFENESIN SALBUTAMOL

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GAVLIN®
100 mg/2 mg CAPSULE
Expectorant / Selective
Beta-2-Adrenoreceptor Agonist

FORMULATION
Each capsule contains:
Guaifenesin ..... 100 mg
Salbutamol (as sulfate)..... 2 mg

DESCRIPTION
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 mucolytic 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 the viscosity of tenacious sputum and is used an expectorant.
On the other hand, Salbutamol is a direct acting sympathomimetic agent with predominantly beta-adrenergic activity and selective action on beta2 receptors. It is used as a bronchodilator. It has more prolonged actions than isoprenaline and as a predominantly beta2 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 urine 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 on them.

PRODUCT DESCRIPTION
White to off-white powder encapsulated in EGC size #3 (cap: dark green, body: standard grey).

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Salbutamol is a selective β adrenoreceptor agonist. At therapeutic doses it acts on the β adrenoreceptors of bronchial muscle, with little or no action on the β adrenoreceptors of cardiac muscle.

Pharmacokinetics
Salbutamol administered intravenously has a half-life of 4 to 6 hours and is cleared partly renally and partly by metabolism to the inactive 4'-O-sulfate (phenolic sulfate) which is also excreted primarily in the urine. The faeces are a minor route of excretion. The majority of a dose of salbutamol given intravenously, orally or by inhalation is excreted within 72 hours. Salbutamol is bound to plasma proteins to the extent of 10%.

After oral administration, salbutamol is absorbed from the gastrointestinal tract and undergoes considerable first-pass metabolism to the phenolic sulfate. Both unchanged drug and conjugate are excreted primarily in the urine. The bioavailability of orally administered salbutamol is about 50%.

Pre-clinical Safety Data
In common with other potent selective β receptor agonists, salbutamol has been shown to be teratogenic in mice when given subcutaneously. In a reproductive study, 9.3% of foetuses were found to have cleft palate, at 2.5mg/kg, 4 times the maximum human oral dose. In rats, treatment at the levels of 0.5, 2.32, 10.75 and 50mg/kg/day orally throughout pregnancy resulted in no significant foetal abnormalities. The only toxic effect was an increase in neonatal mortality at the highest dose level as the result of lack of maternal care. A reproductive study in rabbits revealed cranial malformations in 37% of foetuses at 50mg/kg/day, 78 times the maximum human oral dose.

DRUG INTERACTION
Salbutamol and non-selective β-blocking drugs, such as propranolol, should not usually be prescribed together.
Salbutamol is not contra-indicated in patients under treatment with monoamine oxidase inhibitors (MAOIs).

INDICATIONS
For the treatment of acute and chronic respiratory tract disorders associated with tenacious mucus secretions or bronchospasm such as acute and chronic bronchitis, asthma and emphysema.

DOSAGE AND MODE OF ADMINISTRATION
Adult : 1—2 Capsules
Children : 6—12 years 1 capsule
To be taken two to three times a day.
Or as prescribed by the physician.

ADVERSE REACTIONS
Fine tremor skeletal muscle, feeling of tension, peripheral vasodilation, a compensatory small increase in heart rate, headache, transient muscle cramps, hypersensitivity reactions, hyperactivity in children. Risk of dental caries.

PREGNANCY AND LACTATION
Administration of drugs during pregnancy should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus.

During worldwide marketing experience, rare cases of various congenital anomalies, including cleft palate and limb defects have been reported in the ofspring of patients being treated with salbutamol. Some of the mothers were taking multiple medications during their pregnancies. Because no consistent pattern of defects can be discerned, and baseline rate for congenital anomalies is 2-3%, a relationship with salbutamol use cannot be established.

As salbutamol is probably secreted in breast milk its use in nursing mothers is not recommended unless the expected benefits outweigh any potential risk. It is not known whether salbutamol in breast milk has a harmful effect on the neonate.

OVERDOSAGE
The preferred antidote for overdosage with salbutamol is a cardioselective β-blocking agent. However, β-blocking drugs should be used with caution in patients with a history of bronchospasm. Hypokalaemia may occur following overdose with salbutamol. Serum potassium levels should be monitored.

WARNINGS & PRECAUTIONS
The management of asthma should normally follow a stepwise programmed, and patient response should be monitored clinically and by lung function tests. Increasing use of short-acting inhaled β agonists to control symptoms indicates deterioration of asthma control. Under these conditions, the patient's therapy plan should be reassessed. Sudden and progressive deterioration in asthma control is potentially life-threatening and consideration should be given to starting or increasing corticosteroid therapy. In patients considered at risk, daily peak flow monitoring may be instituted.

Patients should be warned that if either the usual relief is diminished or the usual duration of action reduced, they should not increase the dose or its frequency of administration, but should seek medical advice.

Salbutamol should be administered cautiously to patients with thyrotoxicosis.

Potentially serious hypokalaemia may result from β agonist therapy mainly from parenteral and nebulised administration. Particular caution is advised in acute severe asthma as this effect may be potentiated by concomitant treatment with xanthine derivatives, steroids, diuretics and by hypoxia. It is recommended that serum potassium levels are monitored in such situations.

In common with other β-adrenoceptor agonists, Salbutamol can induce reversible metabolic changes, for example increased blood sugar levels. The diabetic patient may be unable to compensate for this and the development of ketoacidosis has been reported. Concurrent administration of corticosteroids can exaggerate this effect.

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.

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

STORAGE CONDITION
Store at temperatures not exceeding 30ºC.

AVAILABILITY
Alu/Clear PVDC Blister Pack x 10's (box of 100's)

REGISTRATION NUMBER
DRP-6278

DATE OF FIRST AUTHORIZATION/RENEWAL
July 31, 2015

Manufactured by:
JM TOLMANN LABORATORIES, INC.
#95 North Zuzuarregui St., Diliman, Q. C.

170 mm

105 mm

INSERT Required size:
105 mm x 170 mm
UNFOLDED