SALBUTAMOL + GUAIFENESIN

VENTO-BRONCHO G

1 mg/50 mg per 5 mL SYRUP

℞ ANTI - ASTHMA / EXPECTORANT

FORMULATION:
Each 5 mL (one teaspoonful) contains.
Salbutamol .....1 mg
(Equivalent to Salbutamol Sulfate 1.2 mg)
Guaifenesin.....50 mg

DESCRIPTION:
Salbutamol a white or almost white crystalline powder. Freely soluble in water; practically insoluble or very slightly soluble in alcohol and in dichloromethane.
Salbutamol and salbutamol sulfate are used as bronchodilators in the management of reversible airways obstruction, as in asthma and in some patients withchronic obstructive pulmonary disease.
Guaifenesin a white to slightly gray crystalline powder. May have a slight characteristic odor. Soluble 1 in 60 to 70 of water; soluble in alcohol, in chloroform, and in propylene glycol; sparingly soluble in glycerol.
Guaifenesin is reported to increase the volume and reduce the viscosity of tenacious sputum and is used as an expectorant for productive cough.
The combination of salbutamol with guaifenesin is designed to relieve respiratory obstruction and improve pulmonary ventilation. Respiratory disorders where bronchospasm and excessive secretion of tenacious mucus are complicating factors, eg, bronchial asthma, chronic bronchitis and emphysema. Productive cough as in bronchitis, bronchial asthma, pneumonia and other acute respiratory tract infections.
VENTO-BRONCHO G - is clear, colorless syrup liquid in sweet cherry flavor. Boston round, Amber Bottle with Aluminum Cap x 60 mL and 120 mL (Box 1's).

PHARMACOLOGY:
Salbutamol is a selective beta 2-adrenoceptor agonist. At therapeutic doses it acts on the beta 2-adrenoceptor of bronchial muscle with or no action on the beta 1-adrenoceptors of the heart. Guaifenesin can make the viscous mucus of the respiratory pathway more in the presence of excessive mucus adequate pulmonary to remove mucus obstruction. The combination of salbutamol and guaifenesin is designed to relieve respiratory obstruction and improve pulmonary ventilation.

WHAT IS IN THE MEDICINE?
Salbutamol is a selective β2-adrenoceptor agonist indicated for the treatment or prevention of bronchospasm. It provides short-acting (4 hrs) bronchodilation in reversible airways obstruction due to asthma, chronic bronchitis and emphysema. Bronchodilators should not be the only or main treatment in patients with persistent asthma. In patients with persistent asthma unresponsive to salbutamol, treatment with inhaled corticosteroids is recommended to achieve and maintain control. Failing to respond to treatment with salbutamol may signal a need for urgent medical advice or treatment.
The combination of salbutamol with guaifenesin is designed to relieve respiratory obstruction and improve pulmonary ventilation. Respiratory disorders where bronchospasm and excessive secretion of tenacious mucus are complicating factors, eg, bronchial asthma, chronic bronchitis and emphysema.
Productive cough as in bronchitis, bronchial asthma, pneumonia and other acute respiratory tract infections.

STRENGTH OF MEDICINE:
See Formulation

WHAT IS THIS MEDICINE USED FOR?
Treatment or prevention of bronchospasm. Relief of resp obstruction & improves pulmonary ventilation. Respiratory disorders complicated by bronchospasm and excessive secretion of tenacious mucus eg bronchial asthma, chronic bronchitis and emphysema.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE
Two or three times a day.
Adult : 2 to 4 teaspoonfuls
Children : 6 to 12 yrs. old: 2 teaspoonfuls
Under 6 yrs old: 1 to 2 teaspoonfuls. Or as prescribed by the physician.

WHAT YOU NEED TO KNOW BEFORE YOU TAKE VENTO-BRONCHO G SYRUP?
Do not take Vento-Broncho G Syrup:
* If you allergic to salbutamol sulfate or any of the ingredients of this medicine.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?
The management of asthma should normally follow a stepwise program and patient response should be monitored clinically and by lung function tests. Increasing use of short-acting inhaled β2-agonists to control symptoms indicates deterioration of asthma control. Under these conditions, the patient's therapy plan should be re-assessed.
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, the patient 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 hypokalemia may result from β2-agonist therapy mainly from parenteral and nebulized 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 **(VENTO-BRONCHO G)** can induce reversible metabolic changes eg, 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.
Long-term treatment with salbutamol and guaifenesin expectorant syrup (sugar-containing formulation) increases the risk of dental caries. It is important that adequate dental hygiene is maintained.
Patient response should be monitored clinically & by lung function tests. Thyrotoxicosis; acute severe asthma; diabetic patients. Concurrent use w/ corticosteroids. Pregnancy & lactation. Syr: Increased risk of dental caries.

UNDESIRABLE EFFECTS:
Headache, urticaria, hypotension, feeling of tension, hand tremor, peripheral vasodilatation, transient and muscle cramps.

WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?
Salbutamol and nonselective β-blocking drugs eg, propranolol, should not usually be prescribed together.
Salbutamol is not contraindicated in patients under treatment with monoamine oxidase inhibitors (MAOIs).

WHAT SHOULD YOU DO IF YOU MISS ADOSE?
If you miss a dose, just take the next dose and subsequent doses at the usual recommended schedule. Do not double dose.

SIGNS AND SYMPTOMS OF OVERDOSE
The most common signs and symptoms of overdose with salbutamol are transient β-agonist pharmacologically mediated events. Hypokalaemia may occur following overdose with salbutamol. Serum potassium levels should be monitored.Lactic acidosis has been reported in association with high therapeutic doses as well as overdoses of short-acting β-agonist therapy, therefore monitoring for elevated serum lactate and consequent metabolic acidosis (particularly if there is persistence or worsening of tachypnea despite resolution of other signs of bronchospasm such as wheezing) may be indicated in the setting of overdose. Very large doses of guaifenesin cause nausea and vomiting.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?
If you have taken more than the recommended dosage, consult a doctor or contact a Poison Centro Center right away.

HOW SHOULD YOU KEEP THIS MEDICINE?
Store at temperatures not exceeding 30°C

WHEN SHOULD YOU CONSULT YOUR DOCTOR?
Tell your doctor as soon as possible if you notice any of these:
Rare and very rare reactions were generally determined from spontaneous data.
Salbutamol: Immune System Disorders: Very Rare: Hypersensitivity reactions including angioedema, urticaria, bronchospasm, hypotension and collapse. Metabolism and Nutrition Disorders: Rare: Hypokalemia. Potentially serious hypokalemia may result from β2-agonist therapy. Nervous System Disorders: Very Common: Tremor. Common: Headache. Very Rare: Hyperactivity. Cardiac Disorders: Common: Tachycardia, palpitations. Rare: Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles. Vascular Disorders: Rare: Peripheral vasodilatation. Musculoskeletal and Connective Tissue Disorders: Common: Muscle cramps. Very Rare: Feeling of muscle tension.
Guaifenesin: Immune System Disorders: Unknown: Hypersensitivity and allergic reactions including anaphylactic reactions, angioedema, rash; urticaria and dyspnea. Gastrointestinal Disorders: Unknown: Nausea, vomiting, abdominal discomfort.

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

REGISTRATION NO.: DRP - 836

DATE OF FIRST AUTHORIZATION/RENEWAL OF THE THE AUTHORIZATION
05 December 1997

DATE OF REVISION OF PATIENT INFORMATION LEAFLET
10 November 2020

AVAILABILITY:
Bottles of 60 mL and 120 mL.

SHELF - LIFE 36 Months

Manufactured by:
SAN MARINO *Laboratories* CORP.
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Brgy. Javalera, Gen., Trias Cavite